Fondation Cognacq-Jay
HÔPITAL FORCILLES

Evaluation of the impact of the French and international definitions and the type of the muscle assessment tool on the prevalence of undernutrition in hospitalized patients

PROTEIN

PRevalence and muscle OuTcomEs of undErnutritIoN in hospitalized patients

Version n°2 of 14 /12 /2021

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Interventional research involving humans with minimal risk and minimal burden

PRINCIPAL INVESTIGATOR	
Ilham BENHARRATS, internist, Gastro-nutrition Department, Forcilles Hospital	
CO-INVESTIGATORS	
Virginie COLELLA, APA teacher, rehabilitation department, Forcilles Hospital	**Aymeric LE NEINDRE,** physiotherapist, clinical research department, Forcilles Hospital
Carlos DIAZ LOPEZ, physiotherapist, rehabilitation department, Forcilles Hospital	**Mohand TAGZIRT, geriatrician**, Forcilles Hospital, Gastro-nutrition department
Leïla NAHAL, dietician, dietetics department, Forcilles Hospital	**Salima KALLA, Oncologist**, Oncology Department, Forcilles Hospital
Cécile SERON, dietician, dietetics department, Forcilles Hospital	**Maxime CADORET,** dietician, dietetics department, Forcilles Hospital
Tom BARBOSA, APA teacher, Rehabilitation Department, Forcilles Hospital	**Caroline O'CONNELL,** Respirologist, Department of Respirology, Forcilles Hospital
Sophie VIDAL-JESSEL, diabetologist, obesity-nutrition service, Forcilles Hospital	
METHODOLOGY-STATISTICS	
Philippe AEGERTER, Methodologist, GIRCI Ile-de-France	

Promoter :	**Contact:**
Forcilles Hospital-Cognacq-Jay Foundation Route de Servon 77150 Férolles-Attilly	**Aymeric LE NEINDRE**, Clinical Research Coordinator Tel: 01 60 64 60 93 Mail: **aleneindre@cognacq-jay.fr**

KEY CONTACTS			
FIRST NAME, LAST NAME	**ROLE**	**FUNCTION**	**CONTACT INFORMATION**
Ilham BENHARRATS	Principal investigator	Internist	ibenharrats@cognacq-jay.fr 01.60.64.61.78
Virginie COLELLA	Co-investigator	APA teacher	vcolella@cognacq-jay.fr
Aymeric LE NEINDRE	Co-investigator	Physiotherapist	aleneindre@cognacq-jay.fr
Carlos DIAZ LOPEZ	Co-investigator	Physiotherapist	clopez@cognacq-jay.fr
Salima KALLA	Co-investigator	Oncologist	skalla@cognacq-jay.fr
Leïla NAHAL	Co-investigator	Dietician	lnahal@cognacq-jay.fr
Mohand TAGZIRT	Co-investigator	Geriatrician	mtagzirt@cognacq-jay.fr
Cécile SERON	Co-investigator	Dietician	cseron@cognacq-jay.fr
Maxime CADORET	Co-investigator	Dietician	mcadoret@cognacq-jay.fr
Tom BARBOSA	Co-investigator	APA teacher	tbarbosa@cognacq-jay.fr
Caroline O'CONNELL	Co-investigator	Pneumologist	coconnell@cognacq-jay.fr
Sophie VIDAL-JESSEL ,	Co-investigator	Diabetologist	svidaljessel@cognacq-jay.fr
Philippe AEGERTER	Methodology	Public health doctor	philippe.aegerter@uvsq.fr

PROTOCOL VERSION HISTORY

Version	Date	Reason for the amendment
2	14/12/2021	Requests for changes to the IRB

SUMMARY OF THE RESEARCH

Manager	Forcilles Hospital-Cognacq-Jay Foundation
Person who directs and monitors the research	Aymeric LE NEINDRE
Title	Evaluation of the impact of the French and international definitions and the type of the muscle assessment tool on the prevalence of undernutrition in hospitalized patients
Acronym	PROTEIN
Protocol version	n°2 of 14 /12 /2021
Rationale / context	In France, the prevalence of undernutrition among hospitalized patients varies from 30 to 50%. Undernutrition is strongly associated with a decrease in the patient's functional capacities and an increase in morbidity and mortality and in healthcare costs. In 2019, both the Global Leadership Initiative on Malnutrition (GLIM) and the Haute Autorité de Santé (HAS) published updated diagnostic criteria for undernutrition in adults aged <70 years. Aetiological and phenotypic criteria are retained: reduced food intake, inflammatory state, weight loss, BMI and reduced muscle mass. Reduced muscle mass has become a major diagnostic criterion and various measurement tools are suggested, such as bioelectrical impedancemetry, grip strength measurement or magnetic resonance imaging. Collaboration between dieticians, physiotherapists, nurses, care assistants and doctors makes it possible to respond to the need to screen for undernutrition according to these new definitions, which involve a multidisciplinary assessment. These two definitions are very close but differ on the time period of weight loss, on the BMI cut-off values and on the thresholds for muscle mass loss. The GLIM definition may be less selective than the HAS definition. We hypothesize that the prevalence of undernutrition in a population of adult patients hospitalized in diabetology-obesity, pneumology, oncology and gastro-nutrition, < 70 years old, is different according to the diagnostic criteria recommended by the HAS or by the GLIM, and may be associated with a different patient morbi-mortality. In addition, the choice of the method of assessment of muscle function could impact this prevalence.
Main objective	The main objective of this study is to compare the prevalence of global undernutrition based on the diagnostic criteria recommended by the HAS with that based on the diagnostic criteria recommended by the GLIM, in patients hospitalised in short stay and follow-up and rehabilitation care in diabetology-obesity, pneumology, oncology and gastro-nutrition

Secondary objectives	The secondary objectives will be, for patients hospitalised in short stay and follow-up care and rehabilitation of diabetes-obesity, pneumology, oncology and gastro-nutrition:
	• To compare the prevalence of severe undernutrition between the HAS and GLIM groups;
	• To compare the morbi-mortality of undernutrition between the HAS and GLIM groups on :
	  o Length of stay ;
	  o Mortality rate ;
	  o Autonomy at discharge.
	• To evaluate the impact of the choice of muscle function assessment tool on the prevalence of undernutrition in the HAS and GLIM groups.

Research scheme	Prospective, monocentric, interventional cohort study with minimal risks and constraints falling within the scope of article L.1121-1 of the Public Health Code.
Inclusion criteria	- Admitted to short stay and follow-up care and rehabilitation of diabetes-obesity, pneumology, oncology and gastro-nutrition; - Age between 18 and 70 years at the time of inclusion ; - Affiliation with a social security scheme or beneficiary of such a scheme ; - Oral, free, informed and express consent of the patient or his/her relative.
Non-inclusion criteria	- Inability to perform bioelectrical impedance measurement ; - Patient's refusal to participate in the study ; - Known pregnancy ; - Person subject to a legal protection measure ; - Patient under guardianship or curatorship ; - Patient with limited care ; - Randomisation in the ineligible study group.
Primary endpoint	Prevalence of global undernutrition in patients hospitalised in short stay and follow-up and rehabilitation care for diabetes-obesity, pneumology, oncology and gastro-nutrition, according to the diagnostic methods of the HAS and GLIM
Secondary evaluation criteria	• Prevalences of severe undernutrition according to the HAS and GLIM diagnostic methods; • Morbidity and mortality criteria in the HAS and GLIM moderate and severe undernutrition groups: o Duration of hospital stay (days) ; o Mortality: proportion and date of occurrence of death among patients included during hospitalisation; o Autonomy at discharge: Activities Daily Living score (ADL, Appendix X). • Tools for measuring muscle function : o Bioelectrical impedance measurement ; o Handgrip ; o Walking speed.
Group comparison	Patients hospitalised in short stay and follow-up and rehabilitation care for diabetes-obesity, pneumology, oncology and gastro-nutrition.
Number of subjects needed	260
Expected number of centres	1
Duration of the research	21 months
Statistical analysis of data	Univariate comparisons will use the usual statistical tests after verification of the distribution of the variables (Chi2 or Fisher's test, t-test, anova or their non-parametric equivalents Wilcoxon and Kruskal-Wallis tests). The variables will be compared between the two groups by the appropriate tests according to the type of variables (quantitative or qualitative) and their distribution.
Expected benefits	The results of this study will make it possible to verify whether the GLIM definition increases the prevalence of undernutrition compared to that of the HAS. The use of one or other of the definitions could thus have an impact on the medical and paramedical management of undernutrition. On the other hand, muscle function benefits from different assessment tools, which could lead to a different estimate of the reduction in muscle mass and therefore a different prevalence of undernutrition. The results of our study will help to evaluate this and guide professionals in the choice of tools for assessing muscle function.
Source of funding	Forcilles Hospital-Cognacq-Jay Foundation

Independent Supervisory Committee planned	No

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1 Rationale for the research

1.1 Epidemiology and morbidity of undernutrition

Undernutrition, whether linked to disease, poverty, hunger, war or natural disasters, affects more than 1 billion people worldwide (1). In France, an empirical estimate suggests a prevalence of undernutrition among hospital patients of about 2 million (2) or 30 to 50%. (3). It should be remembered that undernutrition is very common in and out of hospital. It is widely accepted that undernutrition can be caused by a deficit in nutrient intake or malabsorption. However, it is now known that the inflammatory state present during an illness is associated with undernutrition (1). The inflammatory state promotes anorexia and decreased intake but also increases basal metabolic rate and muscle catabolism. Undernutrition is marked by a decrease in all markers of muscle mass (1). It is thus strongly associated with a reduction in the patient's functional capacities and an increase in morbidity and mortality and health costs (1,4–6).

1.2 Definitions of undernutrition

The definition of undernutrition has lacked consensus for many years on the diagnostic criteria to be applied in clinical practice (1,7). In France, undernutrition has been the subject of numerous definitions as shown by the various publications since 1971 (7). Currently, undernutrition is defined as an imbalance in the energy and/or protein balance, producing a measurable change in body functions and/or composition, and worsening the prognosis of diseases (8,9). In France, undernutrition in patients under the age of 70 has long been defined according to the presence of at least one of the following diagnostic criteria (10,11) :

- Weight loss ≥ 10% from previous weight or ≥ 5% in one month;
- BMI ≤ 18.5 kg/m^2 ;
- Albumin level (excluding inflammatory syndrome) < 30g/l ;
- Pre-albumin < 110mg/l.

Undernutrition was qualified as severe if weight loss was greater than 15% in 6 months or ≥ 10% in one month, or if albuminemia excluding inflammatory syndrome was less than 20g/l and pre-albuminemia less than 50 mg/l. This definition did not take into account the impact of undernutrition on the patient's body composition and functional capacities, which are nevertheless the reflection of a significant clinical impact of undernutrition (9,12).

1.3 International consensus on the definition of undernutrition

In 2019, the Global Leadership Initiative on Malnutrition (GLIM) published an international consensus report on diagnostic criteria for undernutrition (1). The diagnostic criteria are numerous, and include aetiological criteria such as reduced food intake; an inflammatory context; symptoms such as anorexia, fatigue; phenotypic criteria such as weight loss, body mass index (BMI), fat to lean mass ratio, fluid retention and muscle function.

GLIM has chosen to retain the most relevant criteria among the etiological and phenotypic criteria:

- Aetiological criteria: reduced food intake and inflammatory state of the patient;
- Phenotypic criteria: weight loss, BMI and reduction in muscle mass.

Muscle mass is described as a major diagnostic criterion, since it is a direct indicator of protein catabolism linked to undernutrition, but also a reflection of functional impairment in the patient, since it is directly associated with functional capacities, autonomy and prognosis (1). Various measurement tools are suggested, such as bioelectrical impedancemetry, ultrasound or magnetic resonance imaging, leaving the choice of tool to the clinicians, depending on experience and local resources. Handgrip measurement is considered a complementary measure. GLIM advises an assessment of the risk of undernutrition, using validated questionnaires such as the NRS (Nutritional Risk Screening) or the MNA-SF (Mini Nutritional Assessment-Short Form). The degree of severity of undernutrition is only assessed on the basis of phenotypic criteria.

1.4 New definition of undernutrition adopted in France

The French National Authority for Health (HAS) revised the definition of undernutrition in adults (< 70 years) in 2019 (7)This definition is very similar to the GLIM definition, but differs in some important respects. It includes the use of aetiological and phenotypic criteria, and now includes the assessment of muscle strength, gait speed and bioelectrical impedancemetry. It is important to note that albuminemia has disappeared from this new definition, in favour of the evaluation of the reduction in food intake and the search for an aggressive situation (acute, chronic progressive or malignant pathology). The albumin level is only used in the severity criteria. This new definition makes it possible to take into account the consequences in terms of body composition and functional capacity of undernutrition, the alteration of which is associated with a poor prognosis (13).

1.5 Convergences and divergences between the international and French definition

In adults under 70 years of age, both the GLIM and the HAS recommend screening for undernutrition, but the HAS recommendations do not recommend the use of a precise tool for assessing the risk of undernutrition. The presence of at least one aetiological criterion and one phenotypic criterion is mandatory to make a diagnosis of undernutrition in both situations. The differences between the international consensus and the HAS recommendations concern the diagnostic criteria used (Table 1).

Table 1: Comparison of the diagnostic criteria for undernutrition between the GLIM (1) and HAS definitions (7).

	Phenotypic criteria			Etiological criteria	
	Weight loss (%)	**Low BMI (kg/m²)**	**Reduction in muscle mass**	**Reduction in food intake or absorption**	**Inflammatory situation**
GLIM	> 5% in the last 6 months or > 10% beyond 6 months	< 20	Reduction assessed by a validated measurement technique*.	≤ 50% of food intake > 1 week or any reduction > 2 weeks, or any gastrointestinal conditions or symptoms impacting assimilation or absorption	Acute or certain chronic or malignant conditions
HAS	≥ 5% in 1 month or ≥ 10% in 6 months or loss ≥ 10% from usual weight before onset of disease	< 18,5	Quantified Reduction** (QR)	Same as	Same as

* Methods of measuring muscle mass proposed by GLIM: Dual X-ray Absorptiometry (DEXA); bioelectrical impedancemetry; CT or MRI. In the absence of these tools, anthropometric measurements such as arm or leg circumference can be used. Grip strength measurement is considered a complementary measure. The cut-off values are those of Cruz et al (14).

** Methods of measuring muscle mass proposed by the HAS:

[3] Méthodes et seuils proposés selon les données les plus récentes à disposition

Méthodes de mesure	**Hommes**	**Femmes**
Force de préhension (dynamomètre) en kg	< 26	< 16
Vitesse de marche (m/s)	< 0,8	< 0,8
Indice de surface musculaire en L3 en cm²/m² (scanner, IRM)	52,4	38,5
Indice de masse musculaire en kg/m² (impédancemétrie)	7,0	5,7
Indice de masse non grasse (impédancemétrie[a]) en kg/m²	< 17	< 15
Masse musculaire appendiculaire (DEXA) en kg/m²	7,23	5,67

The GLIM and HAS diagnostic criteria differ on the time period of weight loss, on the BMI cut-off values and on the tools for measuring muscle mass/strength/function.

The severity of undernutrition can then be determined. It can be moderate or severe. GLIM defines severity solely according to phenotypic criteria, whereas the HAS uses both phenotypic and aetiological criteria (Table 2):

Table 2: Classification of the severity of undernutrition according to GLIM and HAS

	Moderate malnutrition	Severe undernutrition
GLIM	• BMI < 20 kg/m2 • Weight loss of 5-10% in the last 6 months or 10-20% beyond 6 months • Mild to moderate reduction in muscle mass	• BMI < 18.5 kg/m2 • Weight loss of >10% in the last 6 months or >20% beyond 6 months • Severe reduction in muscle mass
HAS	• 17 < BMI < 18.5 kg/m2 • Weight loss ≥ 5% in 1 month or ≥ 10% in 6 months or loss ≥ 10% from usual weight before onset of disease • Measurement of albumin by immuno-electrometry or immunoturbidimetry > 30 g/L and < 35 g/L.	• BMI < 17 kg/m2 • Weight loss ≥ 10% in 1 month or ≥ 15% in 6 months or loss ≥ 15% from usual weight before onset of disease • Measurement of albumin by immuno-electrodelemetry or immunoturbidimetry < 30 g/L

1.6 Roles of professionals in screening for undernutrition

In general, and more particularly in the Forcilles hospital, dieticians have a leading role in the detection of undernutrition (15,16). They carry out prospective monitoring on the patient's admission to hospital, collecting indicators relating to BMI and weight loss, in collaboration with the nurses and care assistants. They also carry out a dietetic consultation to clarify the above criteria, to evaluate the reduction in intake and absorption, in collaboration with the doctor, and to measure body composition, such as bioelectrical impedance measurement.

The evolution of the definition of undernutrition, with an important place in the muscular and functional evaluation of the patient, involves new actors: the physiotherapist and the Adapted Physical Activity Teacher (APAT). Indeed, they have expertise in the evaluation of the patient's muscular function and functional capacities. As part of his diagnostic assessment, the physiotherapist is used to evaluating muscle function by dynamometry (17)As part of the diagnostic assessment, the physiotherapist usually assesses muscle function by dynamometry, as well as the patient's functional capacities by field tests or the use of scores. The EAPA also participates in the performance of field tests.

The collaboration between dieticians, physiotherapists, EAPAs, nurses, care assistants and doctors thus makes it possible to respond to the need to detect undernutrition according to the new definitions.

1.7 Assessment of muscle function

Physiotherapists and EAPAs use different tools to assess different aspects of muscle function, such as strength or walking speed in more functional tests.

Isometric grip strength is strongly correlated with lower limb muscle strength, and is a poor marker of mobility in case of weakness (14). A linear relationship has been observed between grip strength and patient disability as measured by the Katz independence scale (18). In addition, grip strength was found to be a good predictor of the patient's clinical condition (19). The measurement of grip strength, using a dedicated dynamometer, also has the advantage of being simple and reproducible (20) and has reference values adjusted for gender and BMI (21).

Gait speed is another indicator used to assess muscle function. Indeed, it is associated with lower limb strength and is predictive of disability and mobility limitation (14). The usual walking speed is usually measured over a distance of 4 or 6 m and has reference values adjusted for sex and height (19).

Dietitians are also involved in the assessment of muscle function, by measuring body composition in terms of lean and fat mass. They perform bioelectrical impedancemetry, which estimates the volumes of fat and lean body mass by measuring the resistance of biological tissues to a low-intensity, high-frequency electrical current at a distance of sinusoïdal of low intensity and high frequency through electrodes (14). This measurement method is simple to use, inexpensive, reproducible and feasible in bedridden patients (14). It also correlates very well with MRI and reference values are obtained in a variety of adult populations (12,22).

1.8 Research hypothesis

We hypothesise that the prevalence of undernutrition in a population of patients hospitalised in diabetology-obesity, pneumology, oncology and gastro-nutrition, under 70 years of age is different according to the diagnostic criteria recommended by the French National Authority for Health or those recommended by the Global Leadership Initiative on Malnutrition. Moreover, these two definitions could have a different impact on the patient's morbidity and mortality. The choice of the method of assessment of muscle function could impact on this prevalence.

2 Originality of the research

The definitions used in the scientific literature to diagnose undernutrition in hospitalised patients are heterogeneous and make it difficult to compare populations within different studies. The international consensus on the definition of undernutrition could provide a solution to these limitations. The recommendation of a new definition of undernutrition in France, which differs on certain criteria from that of the international consensus, could lead to a different prevalence of undernutrition. To our knowledge, no study has assessed whether the

prevalence of undernutrition according to these two definitions is different in hospitalized patients. Furthermore, no study has assessed the prognostic character of undernutrition according to these two definitions on the morbidity and mortality of these patients. Muscle function plays an important role in these two definitions and different measurement tools are proposed. The predictive capacity of these different tools on undernutrition has never been evaluated or compared.

3 Objective

3.1 Main objective

The main objective of this study is to compare the prevalence of global undernutrition based on the diagnostic criteria recommended by the French National Authority for Health with that based on the diagnostic criteria recommended by the Global Leadership Initiative on Malnutrition , in patients hospitalised in short-stay and follow-up care and rehabilitation in diabetes-obesity, pneumology, oncology and gastro-nutrition.

3.2 Secondary objectives

The secondary objectives will be, for patients hospitalised in short stay and follow-up care and rehabilitation of diabetes-obesity, pneumology, oncology and gastro-nutrition:

- To compare the prevalence of severe undernutrition according to the HAS and GLIM diagnostic criteria ;
- To compare the morbidity and mortality of moderate and severe undernutrition according to the HAS and GLIM diagnostic criteria :
    - Length of stay ;
    - Mortality rate ;
    - Autonomy at discharge.
- To compare the predictive capacity of muscle function assessment tools on undernutrition according to the HAS and GLIM diagnostic criteria .

4 Outcome

4.1 Primary outcome

The main outcome is the prevalence of global undernutrition in patients hospitalised in short stay and follow-up and rehabilitation care for diabetes-obesity, pneumology, oncology and gastro-nutrition, according to the diagnostic methods of the HAS and GLIM.

4.2 Secondary outcomes

The secondary outcomes will be :

- Prevalences of severe undernutrition according to the HAS and GLIM diagnostic methods;
- Morbidity and mortality criteria related to moderate and severe undernutrition according to the HAS and GLIM diagnostic criteria :
    - Duration of hospital stay (days) ;
    - Mortality: proportion and date of occurrence of death among patients included during hospitalisation;
    - Autonomy at discharge: Activities Daily Living score (ADL, **Appendix 1**).
- Measures of muscle function :
    - Bioelectrical impedance measurement ;
    - Handgrip ;
    - Walking speed.

5 Eligibility criteria

5.1 Inclusion criteria

Patients with the following criteria will be included:

- Admitted to short-stay and follow-up care and rehabilitation of diabetes-obesity, pneumology, oncology and gastro-nutrition;
- Age between 18 and 70 years at the time of inclusion ;
- Affiliation with a social security scheme or beneficiary of such a scheme ;
- Oral, free, informed and express consent of the patient.

5.2 Non-inclusion criteria

Patients with the following criteria will not be included:

- Inability to perform bioelectrical impedance measurement ;
- Incapacity to consent ;
- Patient's refusal to participate in the study ;
- Known pregnancy ;
- Person subject to a legal protection measure ;
- Patient under guardianship or curatorship ;
- Patient with limited care ;
- Randomisation in the ineligible study group.

5.3 Recruitment procedures

Patients will be recruited prospectively and consecutively from the departments of diabetes-obesity, pneumology, oncology and gastro-nutrition at the Forcilles Hospital. The dietician of the unit identifies the patients on admission to the department.

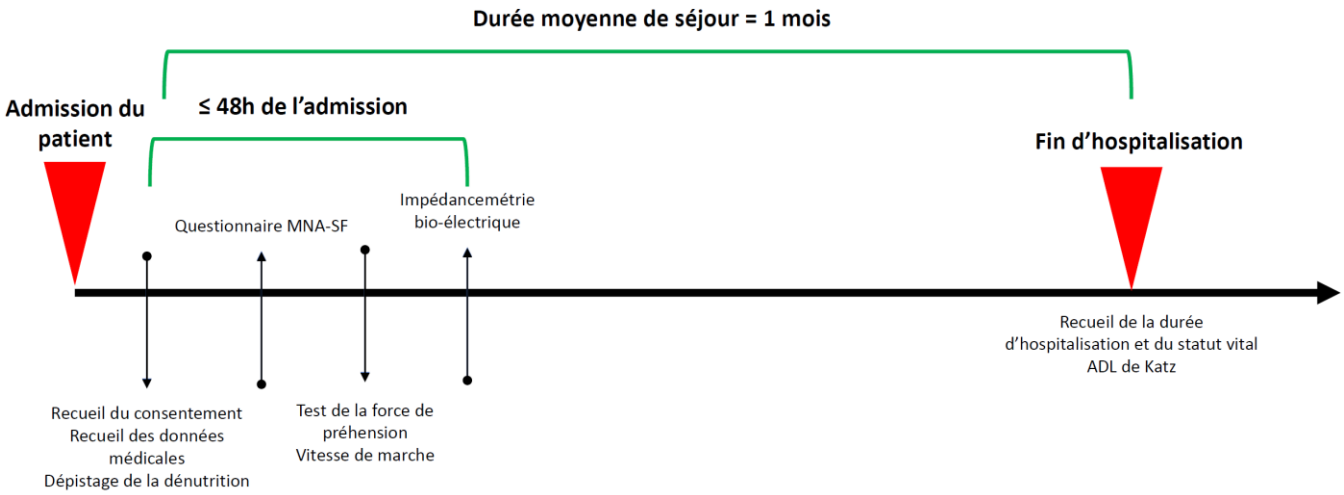
In 2020, according to PMSI data, 1128 patients under 70 years of age were hospitalised in diabetes-obesity, pneumology, oncology and gastro-nutrition. The monthly recruitment target is 13 patients, with a potential of 94 patients per month.

6 Research design

6.1 Type of study

This is a prospective, monocentric, interventional cohort study with minimal risks and constraints falling within the scope of article L.1121-1 of the Public Health Code.
The research will be conducted in accordance with the protocol.

6.2 Research scheme



6.3 Provisional research timeline

The duration of recruitment will be 20 months with follow-up of patients during their entire hospital stay in the care unit, i.e. approximately 30 days (average length of stay), for a total estimated study duration of 21 months.

- Submission to PPC: November 2021
- Start of inclusions: February 2021
- Duration of the inclusion period: 20 months
- Duration of participation of each patient: 30 days
- End of inclusions: October 2023
- Total duration of the research: 21 months
- Conference papers: congresses of medical societies of oncology, surgery, pneumology, nutrition and gastroenterology
- Publication: February 2024

6.4 Location of the study

The study will take place at the Forcilles Hospital, in the short stay and follow-up care and rehabilitation departments of diabetology-obesity, pneumology, oncology and gastro-nutrition.

7 Description of the usual care

7.1 Usual course of treatment

Patients admitted to short stay and follow-up and rehabilitation care for diabetes-obesity, pneumology, oncology and gastro-nutrition benefit from medical, nursing and rehabilitation examinations and care. All of this care will not be modified in the framework of this protocol. Physiotherapists and dieticians carry out their diagnostic assessment and rehabilitation on medical prescription. The EAPAs participate in the functional evaluation of the patient and carry out physical activities adapted to the patient, also on medical prescription.

As part of the screening for undernutrition in our establishment, the dieticians carry out a prospective and systematic collection of the patient's weight and its evolution over the last few months, their BMI and an evaluation of their food intake, within 48 hours of the patient's admission to the department. The estimation of the patient's intake is carried out in collaboration with the nursing assistant.

The nurse's aide carries out a systematic measurement of grip strength when the patient is admitted to the ward (**Appendix 2**). A plan to train the nursing assistants to carry out this measurement has been put in place by the physiotherapists.

The physiotherapist or EAPA carries out the measurement of the patient's walking speed systematically on admission to one of these services (**Appendix 3**).

7.2 Standard assessment procedures

7.2.1 Nutritional assessment

At the time of the patient's admission, a dietary assessment is carried out by the dietician in accordance with the recommendations issued by the French Association of Dieticians-Nutritionists (AFDN) and the HAS. The dietician collects all the data required to detect malnutrition, such as weight, height, BMI, albumin levels, as well as grip strength and walking speed (carried out by the care assistant and the physiotherapist or the EAPA). The dietician also looks for possible barriers to feeding such as dental condition, swallowing problems or digestive discomfort.

The doctor looks for various pathologies impacting on digestive absorption such as short stool syndromes, gastrectomies, pancreatic insufficiency etc. He also looks for aggressive factors

such as cancers, chronic progressive diseases, infections etc. He also looks for factors of aggression such as cancers, chronic progressive diseases, infections etc.
All of these data make it possible to estimate the theoretical nutritional needs of the patient and to adapt the nutritional management. A follow-up of the ingestations is carried out by the dietician in collaboration with the nurses' aides.

7.2.2 Anthropometric measurements

On admission, the ward's nurses and orderlies measure the patient's weight and height. When the patient can maintain an upright position, a conventional scale and a measuring rod are used for the measurements. If the patient cannot maintain this position, a weighing chair and a laser meter are used.
In order to assess weight loss prior to hospitalisation, the previous weight is sought in a hospital report or other recent medical document. Contact with the attending physician is also made in order to obtain information about the patient's weight monitoring. When this information is not available, the previous weight given by the patient is collected.

7.2.3 Biological measurements

On admission, a biological sample is usually taken from patients at risk of undernutrition in order to measure pre-albumin, albumin and C-reactive protein (CRP). These elements make it possible to determine the severity of undernutrition when it is present, according to the diagnostic criteria of the HAS.

7.2.4 Measures of muscle function

Handgrip force measurement ("Handgrip ")

The grip strength is assessed with the Jamar® hydraulic dynamometer by the caregiver.
The patient is in a seated position, on a chair with a backrest, with the feet on the floor. The device is placed in the patient's hand. The patient is instructed to squeeze the dynamometer as hard as possible.
The measurement is taken on the dominant side of the patient. The homolateral shoulder is in adduction (elbow to body), without extension or flexion and in neutral rotation. The elbow is bent to 90° and in neutral pronation. The wrist is in neutral position. Three trials will be carried out, and the best value (in Kg) of the different trials is retained (see measurement procedure in **Appendix 2**).

Gait speed measurement

Walking speed (m/s) is measured on a 4-metre course in a corridor by the EAPA or physiotherapist. The course is marked out on the ground. There are also 1 metre run-up and deceleration zones. The patient is instructed to walk the course at a normal speed and not to complete the distance as quickly as possible. The course is completed 3 times and the best time (in seconds) is recorded (see procedure in **Annex 3**).

8 Evaluation procedure added by the research

8.1 Mini-Nutritional Assessment Short Version (MNA-SF) score

The MNA-SF is a validated nutritional risk screening tool that can be applied by health professionals (see **Appendix 4**). It was developed by Rubenstein (23)based on the MNA.
Completed in less than five minutes, it can identify a decrease in food intake, acute pathology or stress and a drop in BMI. It also includes two questions related to the frailty of the elderly, mobility and neuropsychological problems (dementia, depression).
The MNA-SF classifies people as "undernourished" with a score between 0 and 7 points, "at risk of undernutrition" with a score between 8 and 11 points and "satisfactory nutritional status" with a score between 12 and 14 points. Patients considered "undernourished" and "at risk of undernutrition" should have their nutritional status assessed.

8.2 Diagnosis of undernutrition according to the GLIM criteria

The diagnosis of undernutrition will also be carried out in the framework of this research according to the GLIM criteria. It will be based on the search for at least 1 phenotypic criterion and 1 etiological criterion. Severe undernutrition will be based solely on phenotypic criteria. See detailed description in section 10.1.
This diagnosis according to the GLIM definition will be made by one of the investigators not involved in the management of the patient. The patient's team will be blinded to these results so as not to influence the management of the patient.

8.3 Impedance measurement bio-electrical

Bioelectrical impedance measurement is carried out in the patient's room using the Z-Metrix impedance meter from Bioparhom. The test is carried out when the patient is admitted to the ward.
The patient is positioned in the supine position, inclined at 30 degrees. The patient must rest for at least 15 minutes before the measurement. Four electrodes are placed:

- On the flat of the back of the hand;

- In the wrist at the level of the head of the ulna, in the intertendinous hollow;
- At the ankle, above the lateral malleolus ;
- Above the previous electrode, spaced about 4 fingerbreadths apart.

This non-invasive test quantifies muscle, lean and fat mass as well as bone and water mass. Values are expressed in kilograms and as a percentage of body weight (see measurement procedure in **Appendix 5**).

The following clues will be collected:

- Muscle mass index (in kg/m^2);
- Non-fat mass index (in kg/m^2).

9 Conduct of the research

9.1 Pre-inclusion visit

9.1.1 Checking inclusion and non-inclusion criteria

When a patient is admitted to short-stay and follow-up care and rehabilitation in diabetes-obesity, pneumology, oncology and gastro-nutrition, one of the investigators checks the presence of the inclusion criteria and the absence of the non-inclusion criteria in the institution's computerised medical record.

9.1.2 Sampling of the population

A potential of 94 patients per month eligible for this study are admitted in the short stay and follow-up care and rehabilitation of diabetology-obesity, pneumology, oncology and gastro-nutrition. We anticipate a maximum inclusion of 13 patients per month for logistical reasons.

In order to obtain a representative sample of this patient population in the study, we will sample the patient population on admission , if they meet the eligibility criteria and before the patient is informed and consents are obtained. The patient will be randomly assigned to either the eligible or the ineligible group of the study. Patients in the ineligible group will therefore not be included in the study, but the number of such patients will be collected.

Patients will be sampled via a centralised randomisation system available via the internet, according to a pre-determined randomisation list. The randomisation list will be scheduled in advance by the study statistician. The sampling will be stratified on the care service, and unbalanced using random blocks in order to obtain a number of eligible patients of 15 patients per month (in order to take into account possible refusals of participation). Only the hospital research coordinator will know the randomisation list.

9.1.3 Patient information and consent

When all the criteria allow the inclusion of the patient, the investigator informs the patient of the purpose of the study during a visit to the room. The investigator provides the patient with all the information described in the information note (**Appendix 6**) and, if necessary, obtains the patient's free, informed and express oral consent. This consent will be recorded in the patient's computerised medical record.

The state of consciousness of certain patients (confusion, cognitive disorders) at the time of their admission will not allow them to receive information related to the research and the collection of consent and the information will be given to the person close to them who has been declared a trusted person (**Appendix 7**). At any time, if the patient's neurological or cognitive state permits, he or she will be informed of this research and asked to give express oral consent for the possible continuation of the research (**Appendix 8**).

In the event of a new ban on visits to hospital wards due to the health crisis, information and oral consent from the trusted support person will be given by telephone or video conference.

9.2 Inclusion visit

The inclusion visit will take place within 48 hours of the patient or relative consenting to participate in the study. The following data will be collected:

- Age, weight, height, BMI, gender (male/female) ;
- Hospitalization service ;
- Reason for hospitalisation ;
- Background;
- Reduction in food intake or absorption ;
- Inflammatory situation ;
- Biological markers (albumin, pre-albumin, CRP) if applicable;
- Nutritional data (weight evolution over the last months, theoretical needs, ingestas) ;
- Mini-Nutritional Assessment Short-Form (MNA-SF);
- Autonomy score (Katz ADL) ;
- Bioelectrical impedance data ;
- Grip force (Handgrip) ;
- Walking speed.

9.3 End of research visit

The end-of-research visit will take place when the patient is discharged from hospital or dies. The following data will be collected:

- Duration of hospital stay (in days) ;
- Vital status (death yes/no) ;
- Autonomy score (Katz ADL).

9.4 Summary table

	Pre-inclusion	Inclusion visit	End of research visit
Informing the patient and obtaining consent			
Collection of basic data (age, weight, sex, BMI, medical history)			
Collection of service and reason for hospitalisation			
Associated diseases			
Biomarkers			
Nutritional data			
MNA-SF			
Bioelectrical impedance measurement			
Handgrip, Walking speed			
Katz ADL			
Vital status			
Length of stay in hospital			

10 Definition of evaluation criteria and measurement techniques

10.1 Prevalence of undernutrition

Undernutrition is defined according to the diagnostic methods of the HAS and GLIM:

	Phenotypic criteria			Etiological criteria	
	Weight loss (%)	**Low BMI (kg/m^2)**	**Reduction in muscle mass**	**Reduction in food intake or absorption**	**Inflammatory situation**
GLIM	> 5% in the last 6 months or > 10% beyond 6 months	< 20	Reduction assessed by a validated measurement technique*.	≤ 50% of food intake > 1 week or any reduction > 2 weeks, or any gastrointestinal conditions or symptoms impacting assimilation or absorption	Acute or certain chronic or malignant conditions
HAS	≥ 5% in 1 month or ≥ 10% in 6 months or loss ≥ 10% from usual weight before onset of disease	< 18,5	Quantified Reduction** (QR)	Same as	Same as

For the GLIM and HAS diagnostic method, the diagnosis of undernutrition is positive if an etiological criterion and a phenotypic criterion are present. The assessment of undernutrition according to GLIM will be preceded by a MNA-SF (**Appendix 4**). The methods for measuring the reduction in muscle mass are described in section "**7.2.4. Measurement of muscle function**".

Among patients with undernutrition, severe undernutrition is defined by :

	Moderate undernutrition	Severe undernutrition
GLIM	• BMI < 20 kg/m2 • Weight loss of 5-10% in the last 6 months or 10-20% beyond 6 months • Mild to moderate reduction in muscle mass	• BMI < 18.5 kg/m2 • Weight loss of >10% in the last 6 months or >20% beyond 6 months • Severe reduction in muscle mass
HAS	• 17 < BMI < 18.5 kg/m2 • Weight loss ≥ 5% in 1 month or ≥ 10% in 6 months or loss ≥ 10% from usual weight before onset of disease • Measurement of albumin by immuno-electrometry or immunoturbidimetry > 30 g/L and < 35 g/L.	• BMI < 17 kg/m2 • Weight loss ≥ 10% in 1 month or ≥ 15% in 6 months or loss ≥ 15% from usual weight before onset of disease • Measurement of albumin by immuno-electrodelemetry or immunoturbidimetry < 30 g/L

The prevalence of undernutrition is defined as the proportion of patients with moderate and/or severe undernutrition among the patients included in the study.

10.2 Bioelectrical impedance measurement

According to the physiological model of body composition, 5 compartments are defined (24) :

- Lean mass is the sum of water, bones and organs, excluding the fatty part. It is composed of :
    - The active cell mass (all the cells of the various organs and muscles);
    - Extracellular water (all interstitial fluids and plasma) ;
    - Bone mineral mass (tricalcium phosphate crystals in the skeleton) ;
- The fat mass corresponds to the triglycerides stored in the adipocytes, whatever their anatomical location; this compartment is virtually devoid of water.

Bioelectrical impedance measurement is based on the ability of hydrated tissue to conduct electrical energy. Impedance is a function of the volume of the hydro-electrolyte compartment in the body. The impedance (Z) of a body is related to the specific resistance (r), the length (L), and the conductive volume (V): V = r L2/Z

According to the physiological model, fat mass is waterless and lean mass contains a fixed proportion (73%). From the estimated total body water, it is therefore easy to calculate the lean mass.

Water volumes (total body, extracellular, and intracellular) can be determined. Due to the characteristics of the current, the measurement is completely painless. When the current frequency is higher than 50 kHz, the measured volume is equal to the total body water. When the frequency is lower than 5 kHz, the volume is extracellular water. Measurements with several current frequencies allow an approach to the different water sectors.

Non-fat mass index and muscle mass index in kg/m^2 will be measured (see normal values in **Appendix 5**).

10.3 Morbidity and mortality criteria

10.3.1 Length of stay in hospital

The duration of hospitalisation is defined as the number of days of presence in the inclusion ward, from the patient's admission to the final discharge. Temporary transfers to another hospital department for an examination or an intervention are not considered as discharges.

A special statistical treatment (**described in section 11.4**) will be carried out on the length of hospital stay, given the impact of death on the length of stay.

10.3.2 Mortality

Number of deaths out of the total number of patients included. A special statistical treatment (**described in section 11.4**) will be performed on the mortality rate.

10.3.3 Katz Activities Daily Living (ADL) score

The Katz ADL score (**Appendix 1**) is completed within 48 hours prior to (scheduled) discharge from hospital by the patient's nurse or nurse's aide. The total score is out of 6. A score of less than 3 indicates major dependence, a score of 0 indicates total dependence.
The Katz ADL score will be treated as a discrete numerical variable.

11 Statistical aspects

11.1 Calculation of the number of subjects needed

According to PMSI data, the prevalence of undernutrition according to HAS recommendations was 34%. Taking into account the wider period of weight loss and the higher BMI threshold used by GLIM in its definition of undernutrition, we estimate a higher prevalence of undernutrition. In the absence of data in the literature, we estimate a prevalence of undernutrition according to the GLIM definition at 49%, a difference of at least 15%. We wish to highlight this discrepancy. With a risk $\alpha = 0.05$ and a power of 80%, it will be necessary to include 260 patients.

11.2 General aspects

Descriptive statistics will be based on means (+/- standard deviation) or medians [interquartile range] depending on the distribution of quantitative variables. Qualitative variables will be described in terms of numbers and percentages. Univariate comparisons will use the usual statistical tests after checking the distribution of the variables (Chi2 or Fisher's test, t-test, anova or their non-parametric equivalents Wilcoxon and Kruskal-Wallis tests). Paired sample tests will be used if necessary.

The tests will be performed at the 5% significance level. The 95% confidence intervals will be provided for each estimate.

The calculations will be done using SPSS v21 IBM and R software (version 3.6.1, http://www.R-project.org).

11.3 Main objective

The difference between the prevalences of global undernutrition between the HAS and GLIM groups will be compared using the McNemar test, designed for the comparison of proportions in matched samples.

11.4 Secondary objectives

11.4.1 Comparison of the prevalence of severe undernutrition

The difference between the prevalences of severe undernutrition between the HAS and GLIM groups will be compared using the test described in the main objective.

11.4.2 Comparison of morbidity and mortality

Morbidity and mortality will be compared between the HAS and GLIM groups, for moderate and severe undernutrition, by comparing the length of hospital stay, mortality and autonomy at discharge.

Length of stay in hospital

There is a relationship between the incidence of mortality and all length of stay variables. Length of stay will therefore be analysed using a competitive risk method, which takes into account the fact that patients who die are no longer eligible for length of stay analysis (25).
The estimator also provides the probability of in-hospital death, so that the probability of hospital discharge versus death at any time after inclusion in the study can be assessed simultaneously.

Mortality rate

The estimation of mortality rates will be carried out by the Kaplan and Meier method. The comparison of the 2 curves will be performed by a Logrank test. The mortality rates in the 2 groups will be estimated via the survival curves.

ADL

The ADL score will be compared between the 2 groups using the discrete numerical variable comparison tests described in the general aspects.

11.4.3 Comparison of muscle function assessment tools

The impact of the choice of muscle function assessment tool will be assessed by comparing the prevalence of undernutrition diagnosed with each tool and by comparing the presence of reduced muscle mass with each tool.

12 Expected results in terms of scientific and professional advances

The results of this study will make it possible to verify whether the GLIM definition increases the prevalence of undernutrition compared to that of the HAS. The use of one or other of the definitions could thus have an impact on the medical and paramedical management of undernutrition. On the other hand, muscle function benefits from various assessment tools. These tools assess different aspects of the muscle, such as strength, functional performance or quantity. Muscle function has an important place in the new definitions of undernutrition, thus involving physiotherapists and EAPAs in addition to dieticians, nurses, care assistants and physicians in the screening for undernutrition. The different tools could lead to a different estimation of the reduction of muscle mass and thus a different prevalence of undernutrition. The results of our study will help to evaluate this and guide professionals in the choice of tools for assessing muscle function.

13 Expected benefits and risks for patients

13.1 Minimal risks and constraints added by the research

All medical and paramedical examinations and management are usually carried out with the exception of the MNA-SF questionnaire and bioelectrical impedancemetry, which will be carried out systematically in the patients included. The MNA-SF questionnaire is very quick (less than 5 minutes) and therefore causes very little inconvenience to the patient apart from an additional visit by a carer. Bioelectrical impedancemetry is a tool for assessing body composition using electrodes applied to the skin surface. The examination takes an average of 15 minutes, and is non-invasive and painless. The minimal stress is related to the placement of the electrode and the duration of the examination.

13.2 Expected benefits for the patient

This study could highlight a difference in the prevalence of undernutrition according to the definitions and tools used. The results of this study will not provide direct benefits for the patient, but could allow the clinician to be more vigilant if undernutrition is underestimated, according to the criteria used in France. The benefit would then be a broader screening of undernutrition and would allow the adaptation of the patient's nutritional and rehabilitation management.

14 Feasibility

Taking into account the inclusion and non-inclusion criteria, possible refusals of patients to participate in the research, potential exclusions and recruitment experience, we estimate a minimum recruitment capacity of 50% of patients admitted to short-stay and follow-up and rehabilitation care for diabetes-obesity, pneumology, oncology and gastro-nutrition, i.e. 47 patients per month, with a monthly recruitment target of 13 patients over 20 months.
In addition, screening for undernutrition is usually carried out on all patients admitted to these wards within our establishment. Dieticians, nursing assistants, nurses and doctors are therefore trained and used to carrying out this screening. Bioelectrical impedance measurement by dieticians is already performed on some patients, and takes no more than 15 minutes. The addition of this test to the research framework is therefore feasible.
In addition, the teams have experience in clinical research, as they are already involved in other research projects as promoters and investigating centres. The medical and rehabilitation teams are involved in other ongoing research projects (https://clinicaltrials.gov/ct2/show/NCT02881814https://clinicaltrials.gov/ct2/show/NCT02474797 and https://clinicaltrials.gov/ct2/show/NCT04373811).

15 Ethical and regulatory aspects

The Forcilles-Fondation Cognacq-Jay hospital promoter and the person(s) directing and supervising the research undertake to ensure that this research is carried out in accordance with law n°2004-806 of 9 August 2004 relating to public health policy and the regulatory provisions in force (articles L.1121-1, L.1121-2 and L.1121-3 of the Public Health Code. The data recorded during this research will be subject to computerised processing in compliance with law n°78-17 of 6 January 1978 relating to information technology, files and freedoms, amended by law n° 2018-493 of 20 June 2018 (decree n° 2018-687 of 1° August 2018) and order n° 2018-1125 of 12 December 2018.
The research will be conducted in accordance with this protocol.

15.1 Role of the promoter

The research commission of the Forcilles-Fondation Cognacq-Jay hospital, promoter of this research, submits the file to the opinion of the relevant Comité de Protection des Personnes (CPP) (CPP Ile de France 2) whose opinion will be notified in the information note intended for the persons concerned.
The natural or legal person who initiates the research, manages it and ensures that it is financed is called the sponsor.

15.2 Submission to the PPC

This research will be submitted to a Committee for the Protection of Individuals, which will be drawn by lot within the framework of the "Jardé law" (article L.1121-4 of the Public Health Code, decree no. 2016-1537 of 16 November 2016, which came into force on 18 November 2016).
The opinion of the above-mentioned committee is notified in the information note intended for the persons concerned. A copy of this opinion and a summary of the research will be sent to the ANSM.

15.3 Data protection

This research is subject to law n°78-17 of 6 January 1978 relating to information technology, files and freedoms as amended by law n° 2018-493 of 20 June 2018 (decree n° 2018-687 of 1 August 2018). Information on the rights of persons participating in this research (right of access and rectification, right to object to the transmission of data covered by professional secrecy likely to be used in the context of this research) is included in the information note intended for the patient.

A reference methodology specific to the processing of personal data carried out in the context of biomedical research defined by Law 2004-806 of 9 August 2004 as falling within the scope of Articles L.1121-1 et seq. of the Public Health Code was updated by the CNIL in May 2018 (Deliberation No. 2018-153 of 3 May 2018) following the publication of European Regulation No. 2016/679 (General Data Protection Regulation). This methodology allows a simplified declaration procedure when the nature of the data collected in the research is compatible with the list provided by the CNIL in its reference document. This study is part of the MR001 reference methodology to which the Forcilles-Fondation Cognacq-Jay hospital has committed to comply.

15.4 Insurance

The Sponsor takes out insurance covering its own civil liability and that of any person involved in the performance of the research for the entire duration of the research, regardless of the nature of the links between the participants and the Sponsor (Article L.1121-10 of the Public Health Code). The sponsor is also responsible for the compensation of the harmful consequences of the research for the person who undergoes it and for that of his or her dependents, unless it can be proved that the damage is not attributable to its fault or to that of any other party involved, without the possibility of invoking the act of a third party or the voluntary withdrawal of the person who initially agreed to undergo the research. Where the sponsor is not liable, the victims may be compensated under the conditions set out in Article L.1142-3.

The Forcilles-Fondation Cognacq-Jay hospital has taken out insurance under contract no. 163607 guaranteeing its civil liability as well as that of any intervening party with the company SHAM for the entire duration of the research, in accordance with article L.1121-10 of the Public Health Code.

15.5 Substantial amendment to the protocol

The investigator or coordinator informs the research commission of the Forcilles-Fondation Cogacq-Jay hospital of any proposed modification of the protocol. Any substantial modification will be submitted by the sponsor of this research to the CPP for its opinion.

15.6 Information note and express consent

In accordance with Article L.1122-1 of the Public Health Code, the information provided to the persons who are to be involved in the research is the subject of a written document submitted in advance to the personal protection committee. The ethical opinion of the CPP Ile de France 2 was sought.

The investigator at the centre offers the patient, or a relative if the patient is incapacitated, to participate in the study. The investigator informs the patient orally of the study procedures and gives him/her the information note. If the patient gives free, informed and express oral consent to participate in the protocol, the information given orally and in writing, as well as the collection of oral consent, will be recorded in the patient's medical record.

In the event that a relative of the patient has given consent, as soon as possible, the patient will be informed of the research and asked for oral consent for the possible continuation of the research.

Patients are free to participate or withdraw from the study at any time in accordance with Article 21 of the GDPR. Data collected until the patient withdraws consent will be used unless the patient expressly requests otherwise. The withdrawal of consent by the patient and the agreement to use or not the data previously collected will be traced in the patient's medical file.

When the research is completed, the person who has undergone the research may be informed of the overall results of the research in the manner specified in the information document.

15.7 Expected deadline for publication of results in an international journal

The deadline for the publication of the results is 30 months.

15.8 Data management

For each subject, an identification code (corresponding to the centre number-inclusion number-Initial Surname-Initial First Name) will be assigned. The data collected will be confidential and coded (only the identification code will appear). The concordance table linking the assigned identification code and the participant's name will be kept by the principal investigator at each participating centre in a file with computer restricted access rights. The data will be entered into a password-protected Excel® file. Data processing and statistical analysis will be carried out at the Forcilles-Fondation Cognacq-Jay hospital.

The promoter is responsible for the data and no use or transmission to a third party may be made without his prior agreement.

The specific documents of a type 2 interventional research ("Loi Jardé", decree n° 2016-1537 of 16 November 2016, which came into force on 18 November 2016) with minimal risks and constraints will be archived by all parties for a period of 15 years after the end of the research. This indexed archiving includes:

- successive versions of the protocol (identified by version number and date);
- correspondence;
- the inclusion list or register ;
- the data collection document ;
- research-specific annexes ;
- the final report of the research.

The database that gave rise to the statistical analysis must also be archived by the person responsible for the analysis (paper or computer).

15.9 Human and financial resources

The Forcilles-Fondation Cognacq-Jay hospital is equipped with human, material and technical resources to carry out this research project.

15.10 Data properties

The Forcilles-Fondation Cognacq-Jay hospital is responsible for the data and no use or transmission to a third party may be made without its prior agreement.

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17 Annexes

17.1 Appendix 1: Katz ADL (Activities in Daily Living) Scale (26)

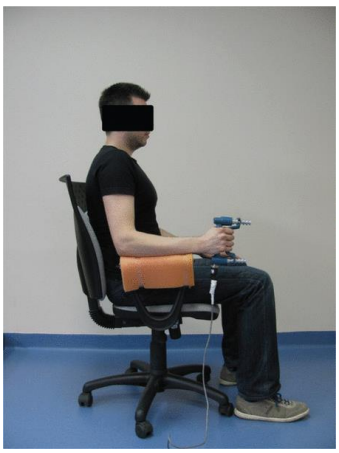
Items	Valeurs	Résultat
Hygiène corporelle		
Autonomie	1	
Aide partielle	0,5	
Dépendant	0	
Habillage		
Autonomie pour le choix des vêtements et l'habillage	1	
Autonomie pour le choix des vêtements et l'habillage, mais a besoin d'aide pour se chausser	0,5	
Dépendant	0	
Aller aux toilettes		
Autonomie pour aller aux toilettes, se déshabiller et se rhabiller ensuite	1	
Doit être accompagné ou a besoin d'aide pour se déshabiller ou se rhabiller	0,5	
Ne peut aller aux toilettes seul	0	
Locomotion		
Autonomie	1	
A besoin d'aide	0,5	
Grabataire	0	
Continence		
Continent	1	
Incontinence occasionnelle	0,5	
Incontinent	0	
Repas		
Mange seul	1	

17.2 Appendix 2: Handgrip Usage Protocol

The patient will be in a seated position, on a chair with a backrest, with the feet on the floor. The shoulder shall be in adduction (elbow to body), without extension or flexion, and in neutral rotation. The elbow shall be placed at 90° of flexion and in neutral pronation-supination. The wrist should also be in neutral position. The practitioner should hold the elbow and the base of the JAMAR force gauge® lightly to avoid changes in positioning. The grip force measurement will consist of 3 measurements on each limb, alternating with a rest (1 minute: time to note the score of the measurement and to quietly settle the person in the position for the next measurement).

The dominant hand will be chosen by the participant by answering the following question: "Are you right or left handed?

The instructions are: "Lean back against the backrest. Take the handle in your hand, keep your elbow close to your body and your forearm straight in front of you" and gradually tighten the handle over 2 to 3 seconds to reach a maximum tightening which must also be maintained for 2 to 3 seconds, without moving the other joints (wrist, elbow and shoulder).
Encouragement will be given to the person during the clamping seconds to motivate the patient as much as possible: "Go ahead and clamp, clamp... hard, HARD! TIGHT! ...and you release". It will be noted if pain appears and limits the grip.



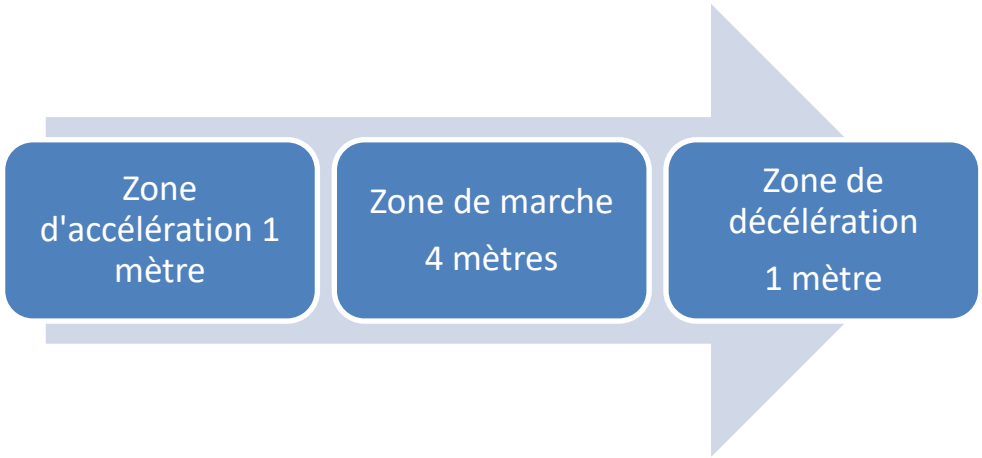
17.3 Appendix 3: Protocol for conducting the Gait speed test

Walking speed (m/s) is measured on a 4-metre course in a corridor. The course is marked out with ground markings. The course is marked out with markings on the floor. 1 metre run-up and run-down zones are also marked out. The patient is instructed to walk the course at a normal speed and not to complete the distance as quickly as possible. The course is completed 3 times and the best time (in seconds) is recorded.

The examiner runs the course at a usual speed and at a maximum speed without running to ensure that the usual speed instruction is well integrated by the patient.

The examiner starts the stopwatch when the first foot crosses the end of the run-up line and stops it when the first foot crosses the 4m line. (See figure below).

The walking speed is determined by dividing the distance by the time taken to walk that distance, giving a result in m/s.



17.4 Annex 4: Mini-Nutritional Assessment Short-Form (MNA-SF) Score (23)

A. Does the patient have a loss of appetite?

Has he/she eaten less in the last 3 months due to lack of appetite, digestive problems, chewing or swallowing difficulties?

0: severe anorexia ;
1: moderate anorexia;
2: no anorexia

B. Recent weight loss (< 3 months)

0: loss > 3 kg ;
1: don't know ;
2: weight loss between 1 and 3 kg;
3: no weight loss

C. Motricity

0: from bed to chair ;
1: stand-alone indoors ;
2: leaving the home

D. Acute illness or psychological stress in the last 3 months?

0: yes ;
2: no

E. Neuropsychological problems

0: severe dementia or depression;
1: moderate dementia or depression;
2: no psychological problems

F. Body Mass Index (BMI) = weight/(height)² in kg/m².

0: BMI < 19 ;

1: 19 < CGI < 21 ;

2: 21 < IMC < 23 ;

3: BMI > 23

Screening score (maximum subtotal = 14 points)

Between 0 and 7 points: malnourished

Between 8 and 11 points: at risk of undernutrition

Between 12 and 14 points: satisfactory nutritional status

17.5 Appendix 5: Impedance measurement protocol bio-electrical

The placement of the electrodes is important for optimal results. For a hemi-body measurement, four electrodes will be placed as shown in Figures 1 and 2.

Figure 1: Placement of electrodes 1 and 2 corresponding to cables 1 and 2.

Be careful, never place the electrode on a bone. The first electrode is placed on the flat of the back of the hand. It is easier to place it if your patient's spot is tight. The second electrode is placed on the wrist at the level of the head of the ulna, in the intertendinous hollow. Figure 1 shows how to place these two electrodes

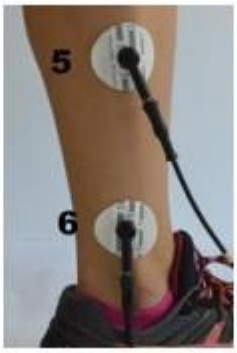


Figure 2: Placement of electrodes 3 and 4 corresponding to cables 3 and 4.

The third electrode is placed on the ankle above the outer malleolus. Finally, to place the last electrode, simply take your hand, put it over the malleolar electrode, count 4 finger crosses and place the fourth electrode. Figure 2 shows how to place these two electrodes.

It is advisable that the patient has removed any jewellery (watch, bracelet) as well as any objects they may have in their pockets. If your connection, the positioning of the device or the quality of the subject's skin cause measurement errors, pop-ups will alert you and advise you to check your connection. Please note that the patient's or user's body should not be in contact with the case or connectors 1 to 4 during the measurement. This can lead to short circuits or parallel currents and thus distort the measurement. The device should not be positioned on the patient. No contact should be made between the hand and the subject's thigh, or between

the thighs. If the thighs of your undressed subject are touching and it cannot be done otherwise, you can put a cloth in contact with the thighs.

Example of results (Figure 3):

The 3 clues will highlight:

- Fat mass, reflects the nutritional status of the patient: Normal if between the gauges, underweight or thin below, overweight between the high and high mark +5%, obese above the high mark +5%;
- Bone content, will reflect bone fragility if the value is below the bottom of the gauge;
- Muscle mass: will reflect the amount of muscle in the body, allows the impact of physical activity and protein intake to be assessed and undernutrition to be detected.

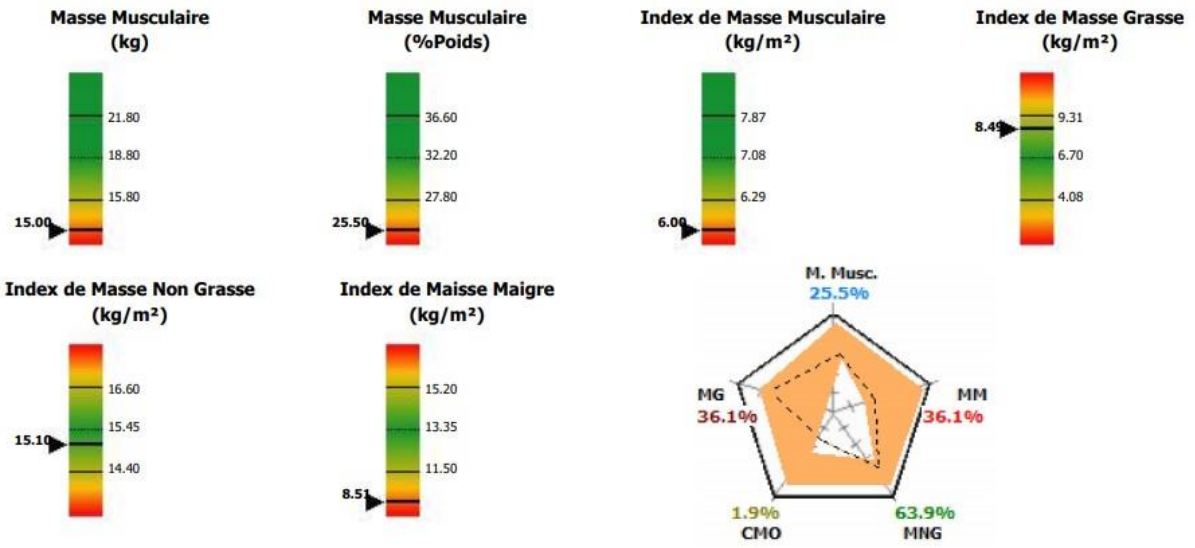


Figure 3: Indices measured with the bio-electrical impedance meter (example of a clinical case)

17.6 Appendix 6: Patient information note

PROTEIN

"Evaluation of the impact of the French and international definitions and of the muscle function measurement tool on the prevalence of undernutrition in hospitalized patients

RCB ID: 2021-A02410-41

PRINCIPAL INVESTIGATOR
Dr Ilham BENHARRATS, internist
Forcilles Hospital
Gastro-Nutrition Service
Route de Servon 77150 Férolles-Attilly
Email : ibenharrats@cognacq-jay.fr

RESEARCH PROMOTER
Clinical Research Office
Forcilles Hospital-Cognacq-Jay Foundation
Route de Servon 77150 Férolles-Attilly
Telephone: 01.60.64.60.93
Fax: 01.60.02.15.09
aleneindre@cognacq-jay.fr

Dear Sir or Madam,

Dr. ....., investigator of the study, practising in the short stay/SSR service of diabetology-obesity/pneumology/oncology/gastro-nutrition of the Forcilles-Fondation Cognacq-Jay hospital, invites you to participate in this research.

Your decision to participate is entirely free and voluntary.

Please read the information below carefully, ask any questions you may have and take as much time as you wish to reflect on your decision to participate in this research.

You are hospitalised in a short stay/SSR diabetes-obesity/pneumology/oncology/gastro-nutrition department as part of the treatment of your pathology or a check-up. Your state of health requires screening for possible malnutrition in order to adapt your medical and paramedical care.

What is the purpose of this research?

The objective of this research is to evaluate the discrepancy between the prevalences of undernutrition as defined by the French National Authority for Health and the Global Leadership Initiative on Malnutrition (international group of experts working on undernutrition). On the other hand, we also wish to compare the different tools for measuring muscle function, which are part of the diagnostic criteria for undernutrition.

How does this research work?

As part of your hospitalization in the department, we propose to study your body composition by performing a bioelectrical impedance measurement.

This examination is painless, non-invasive and risk-free. It is carried out by the dietician by placing 4 electrodes: one on the hand, one on the wrist, one on the ankle and one on the leg. Connected to a computer, they will allow us to measure your lean mass and your fat mass.

The impedance measurement will be performed once, within 48 hours of your admission to the department and will last approximately 15 minutes.

In addition, we will ask you a few questions in the Mini-Nutritional Assessment questionnaire, which will take less than 5 minutes.

Your constraints in this research?

The constraints of this research consist of 1 bio-electrical impedance measurement and 1 questionnaire, for a maximum total duration of 20 minutes.

Possible adverse effects

As your participation in this protocol does not involve any treatment other than that which is currently recommended or other changes to conventional management appropriate to your condition, no adverse effects are expected.

- **No additional treatment will be administered**
- **No additional blood tests will be required**.

Impedance measurement is carried out transcutaneously, i.e. by placing electrodes on your skin. The examination is therefore non-invasive and completely painless.

Your participation in this research will not incur any additional costs compared to those you would have had in the usual follow-up of your disease.

What are the expected benefits of this research?

This study should make it possible to determine whether the use of French or international diagnostic criteria leads to a difference in the prevalence of undernutrition. If one or other of the definitions is associated with a greater prevalence, this will make it possible to monitor and adapt the medical and paramedical management of a greater number of people. In addition, the choice of tool for assessing muscle function could lead to a different estimate of the proportion of muscle mass loss, which is one of the diagnostic criteria for undernutrition. The choice of the tool allowing a wider screening would also allow to adapt the management of the patient.

What are the conditions for participating in this study?

In order to participate in this research, you must be affiliated to or benefit from a social security scheme. However, your participation in this research will not result in any additional costs for you compared to those incurred in the usual care.

Number of patients planned and duration of research?

This research will last 21 months with a 20-month recruitment period to include 266 patients.

What data is collected for the research?

The medical data collected during this study will be processed in a computerised, coded and confidential manner. The main data collected will be anthropometric data (age, weight, height, etc.), related to medical history, nutritional status, biological check-ups, and the results of check-ups by rehabilitation professionals (physiotherapists, dieticians, EAPA). No information bearing your name will be provided to anyone except the doctor in charge of the study and authorised personnel. All data collected will be confidential and coded and analysed in the clinical research office of the Forcilles-Fondation Cognacq-Jay Hospital, the research sponsor. The identification list (correspondence between your study code and your identity) will be kept strictly confidential.

In accordance with the regulations in force, the data will be kept until the final research report is produced and then archived for 15 years.

The data controller is the promoter, Hôpital Forcilles-Fondation Cognacq-Jay, route de Servon 77150 Férolles-Attilly.

Legal basis for data processing

The processing of the data is based on the legitimate interests of the controller, Article 6 paragraph 1 point f, read in conjunction with the necessity of the processing for scientific research purposes, Article 9 paragraph 2 point j, of the European Regulation N° 2016/679 (General Data Protection Regulation, GDPR).

What are your rights?

Your participation in this research is **entirely free and voluntary**. You have the right not to participate in this research.

You cannot be included in an interventional research protocol with minimal risks and constraints without having been informed beforehand. Your doctor must provide you with all the necessary explanations concerning this research, which must comply with the provisions of Article 13 of European Regulation No. 2016/679 (General Data Protection Regulation, GDPR). In accordance with article L.1122-1 of the French Public Health Code, the entire research file has been submitted to the Comité de Protection des Personnes NORD OUEST III which issued a favourable opinion on xx/xx/xxxx.

The Forcilles-Fondation Cognacq-Jay hospital has taken out insurance under contract no. 163607 guaranteeing its civil liability and that of all those involved with the company SHAM.

You can stop participating in the research at any time without justification. This will not affect the quality of the care and treatment provided to you or your relationship with your doctor. The data collected until you withdraw your consent will be used unless you expressly request it. Indeed, in accordance with Article 17 of the GDPR, you have the right to request the deletion of your data already collected. The withdrawal of your consent and the agreement to use or not your previously collected data will be traced in your medical file.

In accordance with the provisions of Articles 15 and 16 of Regulation (EU) 2016/679 of 27 April 2016 (General Data Protection Regulation), you have a right of access, rectification, erasure or restriction of processing. You can find out more about your rights by consulting the CNIL website page https://www.cnil.fr/fr/reglement-europeen-protection-donnees/chapitre3.

In accordance with the provisions of Article 21 of the RGPD, you also have the right to object to the transmission of data likely to be used in the context of this research and to be processed. Your request must be addressed to the Data Protection Officer of the Cognacq-Jay Foundation, either by e-mail to the address dpo@cognacq-jay.fr or by post to the address: Hôpital Forcilles-Fondation Cognacq-Jay, Délégué à la Protection des Données, route de Servon 77150 Férolles-Attilly. You also have the right to lodge a complaint with the Commission Nationale de l'Informatique et des Libertés - CNIL (French personal data control authority, website: www.cnil.fr).

In application of the provisions of article L. 1111-7 of the Public Health Code, you may also access all of your medical data directly or through a doctor of your choice.
Your medical file will remain confidential and can only be consulted under the responsibility of the doctor in charge of your treatment, as well as by the health authorities and by persons duly mandated by the Forcilles-Fondation Cognacq-Jay hospital for research and subject to professional secrecy.
If, after having read all this information and discussed all aspects with the doctor in charge of the research, you have had sufficient time to reflect on your decision and you decide to participate in this research, the research information and your oral consent will be notified and dated in your medical file.

The agreement to participate in this research is free and voluntary.
You may refuse or withdraw your consent at any time without explanation or prejudice.

Any questions?

Dr. _____ (tel. _____) is at your disposal for any further information you may require before and during the research.

17.7 Annex 7: Information note to the relative

PROTEIN

"Evaluation of the impact of the French and international definitions and of the muscle function measurement tool on the prevalence of undernutrition in hospitalized patients

RCB ID: 2021-A02410-41

PRINCIPAL INVESTIGATOR
Dr Ilham BENHARRAT, internist
Forcilles Hospital
Gastro-Nutrition Service
Route de Servon 77150 Férolles-Attilly
Email : ibenharrat@cognacq-jay.fr

RESEARCH PROMOTER
Clinical Research Office
Forcilles Hospital-Cognacq-Jay Foundation
Route de Servon 77150 Férolles-Attilly
Telephone: 01.60.64.60.93
Fax: 01.60.02.15.09
aleneindre@cognacq-jay.fr

Dear Sir or Madam,

Due to his condition which makes him unable to receive and understand the information that will be given to him, we are transmitting to you the information and the proposal of participation of Mr., Ms., Mr. (delete as appropriate) (last name, first name) ..... in the study presented below, under the responsibility of Dr. ....., the investigator of the study

Your opinion on this participation is entirely free and voluntary.

Please read the information below carefully, ask any questions you may have, and take as much time as you wish to reflect on your decision as to whether or not your loved one should participate in this research.

ATTENTION

You can only give your consent :

- if you and the patient you are caring for are not deprived by law of your right to give such consent;

- whether the patient you are caring for is covered by social security;

- if you consider that your decision would probably be that of the patient you are caring for;

- if you feel fully informed;

- if you were able to ask the doctor in charge of the study all the questions you wanted to ask about the research and the way it was going to be carried out and if you consider that you were given satisfactory answers (if, during the study, you have new questions, you can ask them to the doctor in charge of the study, in particular if they concern the interest of the study, the ratio of benefits and risks or the usefulness of collecting certain data from your family member) ;

- if you feel free to give your consent to such participation;

- if you accept that the patient you are caring for may not agree with you and when they get better and are consulted again, do not give consent to continue their participation.

Even if you give your consent today, you may withdraw it at any time and study-related interventions will be stopped as quickly as possible so that no harm is done to the patient. The relationship and quality of current or future care that the patient will receive will not be changed in any way should this occur. The information collected previously to this stop will be used unless you do not want it to be used. You should then inform the patient's doctor who will suggest appropriate medical follow-up.

Your relative is hospitalised in a short stay/SSR diabetes-obesity/pneumology/oncology/gastro-nutrition department as part of the treatment of his or her pathology or for a check-up. His or her state of health requires screening for possible malnutrition in order to adapt medical and paramedical care.

What is the purpose of this research?

The objective of this research is to evaluate the discrepancy between the prevalences of undernutrition as defined by the French National Authority for Health and the Global Leadership Initiative on Malnutrition (international group of experts working on undernutrition). On the other hand, we also wish to compare the different tools for measuring muscle function, which are part of the diagnostic criteria for undernutrition.

How does this research work?

In the context of the hospitalisation of your loved one in the department, we propose to study his or her body composition by carrying out a bio-electrical impedance measurement.

This examination is painless, non-invasive and risk-free. It is carried out by the dietician by placing 4 electrodes: one on the hand, one on the wrist, one on the ankle and one on the leg. Connected to a computer, they will allow us to measure your loved one's lean mass and fat mass.

The impedance measurement will be performed once, within 48 hours of his admission to the department and will last approximately 15 minutes.

In addition, we will ask him some questions in the "Mini-Nutritional Assessment" questionnaire, which will take less than 5 minutes.

The constraints in this research?

The constraints of this research for your loved one consist of 1 bio-electrical impedance measurement and 1 questionnaire, for a total maximum duration of 20 minutes.

Possible adverse effects

As your loved one's participation in this protocol does not involve the administration of any treatment other than that which is currently recommended, nor any other modification of the conventional management adapted to his or her health condition, no adverse effects are expected.

- **No additional treatment will be administered**
- **No additional blood tests will be required**.

Impedance measurement is performed transcutaneously, i.e. by placing electrodes on the skin . The examination is therefore non-invasive and completely painless.

The participation of your loved one in this research will not result in any additional costs compared to those he or she would have had in the usual follow-up of his or her disease.

What are the expected benefits of this research?

This study should make it possible to determine whether the use of French or international diagnostic criteria leads to a difference in the prevalence of undernutrition. If one or other of the definitions is associated with a greater prevalence, this will make it possible to monitor and adapt the medical and paramedical management of a greater number of people. In addition, the choice of tool for assessing muscle function could lead to a different estimate of the proportion of muscle mass loss, which is one of the diagnostic criteria for undernutrition. The choice of the tool allowing a wider screening would also allow to adapt the management of the patient.

What are the conditions for participating in this study?

In order to participate in this research, your relative must be affiliated to or benefit from a social security scheme. However, participation in this research will not entail any additional costs for your family member compared to those incurred in the usual care.

Number of patients planned and duration of research?

This research will last 21 months with a 20-month recruitment period to include 266 patients.

What data is collected for the research?

The medical data collected during this study will be processed in a computerised, coded and confidential manner. The main data collected will be anthropometric data (age, weight, height, etc.), related to medical history, nutritional status, biological check-ups, and the results of check-ups by rehabilitation professionals (physiotherapists, dieticians, EAPA). No information bearing the name of your relative will be provided to anyone except the doctor in charge of the study and authorised personnel. All data collected will be confidential and coded and analysed in the clinical research office of the Forcilles-Fondation Cognacq-Jay Hospital, the research sponsor. The identification list (correspondence between the code of your relative for the study and his/her identity) will be kept strictly confidential.

In accordance with the regulations in force, the data will be kept until the final research report is produced and then archived for 15 years.

The data controller is the promoter, Hôpital Forcilles-Fondation Cognacq-Jay, route de Servon 77150 Férolles-Attilly.

Legal basis for data processing

The processing of the data is based on the legitimate interests of the controller, Article 6 paragraph 1 point f, read in conjunction with the necessity of the processing for scientific research purposes, Article 9 paragraph 2 point j, of the European Regulation N° 2016/679 (General Data Protection Regulation, GDPR).

What are your rights?

Your relative's participation in this research is **entirely free and voluntary**. Your relative's doctor must provide you with all the necessary explanations concerning this research, which must comply with the provisions of Article 13 of European Regulation No. 2016/679 (General Data Protection Regulation, GDPR). In accordance with article L.1122-1 of the Public Health Code, the entire research file has been submitted to the Comité de Protection des Personnes NORD OUEST III which issued a favourable opinion on xx/xx/xxxx.

The Forcilles-Fondation Cognacq-Jay hospital has taken out insurance under contract no. 163607 guaranteeing its civil liability and that of all those involved with the company SHAM.

You can stop your relative's participation in research at any time without justification. This will not affect the quality of the care and treatment provided to your relative or his or her relationship with the doctor. The data collected until the withdrawal of consent will be used unless expressly requested by you. Indeed, in accordance with Article 17 of the RGPD, your loved one has the right to request the deletion of s data concerning already collected. The withdrawal of consent and the agreement to use or not to use the data previously collected will be traced in the medical file of your relative.

In accordance with the provisions of Articles 15 and 16 of Regulation (EU) 2016/679 of 27 April 2016 (General Data Protection Regulation), your loved one has a right of access, rectification, erasure or restriction of processing. You can find out more about your loved one's rights by visiting the CNIL website https://www.cnil.fr/fr/reglement-europeen-protection-donnees/chapitre3. In accordance with the provisions of Article 21 of the RGPD, your relative also has the right to object to the transmission of data likely to be used in the context of this research and to be processed. His/her request must be addressed to the Data Protection Officer of the Cognacq-Jay Foundation, either by e-mail to the address dpo@cognacq-jay.fr or by post to the address: Hôpital Forcilles-Fondation Cognacq-Jay, Délégué à la Protection des Données, route de Servon 77150 Férolles-Attilly. The user also has the right to lodge a complaint with the Commission Nationale de l'Informatique et des Libertés - CNIL (French authority for the control of personal data, website: www.cnil.fr).

In application of the provisions of article L. 1111-7 of the Public Health Code, your relative may also access all medical data concerning him or her directly or through a doctor of his or her choice.

Your relative's medical file will remain confidential and can only be consulted under the responsibility of the doctor in charge of your treatment, as well as by the health authorities and by persons duly mandated by the Forcilles-Fondation Cognacq-Jay hospital for research and subject to professional secrecy.
If, after having read all this information and discussed all aspects with the doctor in charge of the research, you have had sufficient time to reflect on your decision and you agree to your relative taking part in this research, the information about the research and your oral consent will be recorded and dated in your relative's medical file .

The agreement to participate in this research is free and voluntary.
You may refuse or withdraw your consent at any time without explanation or prejudice.

Any questions?

Dr. _____ (tel. _____) is at your disposal for any further information you may require before and during the research.

17.8 Appendix 8: Patient information note for further research

PROTEIN

"Evaluation of the impact of the French and international definitions and of the muscle function measurement tool on the prevalence of undernutrition in hospitalized patients

RCB ID: 2021-A02410-41
PRINCIPAL INVESTIGATOR
Dr Ilham BENHARRAT, internist
Forcilles Hospital
Gastro-Nutrition Service
Route de Servon 77150 Férolles-Attilly
Email : ibenharrat@cognacq-jay.fr

RESEARCH PROMOTER
Clinical Research Office
Forcilles Hospital-Cognacq-Jay Foundation
Route de Servon 77150 Férolles-Attilly
Telephone: 01.60.64.60.93
Fax: 01.60.02.15.09
aleneindre@cognacq-jay.fr

Dear Sir or Madam,

Due to your state of consciousness, we were unable to ask for your prior consent and you were included on ...../...../..... in a research study entitled PROTEIN.

In accordance with the law (article L.1122-1-3 of the Public Health Code), the trusted person that you had designated or your parent/relative was asked to agree to your participation in this research.

Now that you are able to understand and express your wishes, we ask for your consent to continue your participation in this research.
The doctor told you that you were free to accept or refuse further participation in this research.

Your decision to participate is entirely free and voluntary.

Please read the information below carefully, ask any questions you may have and take as much time as you wish to reflect on your decision to participate in this research.

You are hospitalised in a short stay/SSR diabetes-obesity/pneumology/oncology/gastro-nutrition department as part of the treatment of your pathology or a check-up. Your state of health requires screening for possible malnutrition in order to adapt your medical and paramedical care.

What is the purpose of this research?

The objective of this research is to evaluate the discrepancy between the prevalences of undernutrition as defined by the French National Authority for Health and the Global Leadership Initiative on Malnutrition (international group of experts working on undernutrition). On the other hand, we also wish to compare the different tools for measuring muscle function, which are part of the diagnostic criteria for undernutrition.

How does this research work?

As part of your hospitalization in the department, we propose to study your body composition by performing a bioelectrical impedance measurement.

This examination is painless, non-invasive and risk-free. It is carried out by the dietician by placing 4 electrodes: one on the hand, one on the wrist, one on the ankle and one on the leg. Connected to a computer, they will allow us to measure your lean mass and your fat mass.

The impedance measurement will be performed once, within 48 hours of your admission to the department and will last approximately 15 minutes.

In addition, we will ask you a few questions in the Mini-Nutritional Assessment questionnaire, which will take less than 5 minutes.

Your constraints in this research?

The constraints of this research consist of 1 bio-electrical impedance measurement and 1 questionnaire, for a maximum total duration of 20 minutes.

Possible adverse effects

As your participation in this protocol does not involve any treatment other than that which is currently recommended or other changes to conventional management appropriate to your condition, no adverse effects are expected.

- **No additional treatment will be administered**
- **No additional blood tests will be required**.

Impedance measurement is carried out transcutaneously, i.e. by placing electrodes on your skin. The examination is therefore non-invasive and completely painless.

Your participation in this research will not incur any additional costs compared to those you would have had in the usual follow-up of your disease.

What are the expected benefits of this research?

This study should make it possible to determine whether the use of French or international diagnostic criteria leads to a difference in the prevalence of undernutrition. If one or other of the definitions is associated with a greater prevalence, this will make it possible to monitor and adapt the medical and paramedical management of a greater number of people. In addition, the choice of tool for assessing muscle function could lead to a different estimate of the proportion of muscle mass loss, which is one of the diagnostic criteria for undernutrition. The choice of the tool allowing a wider screening would also allow to adapt the management of the patient.

What are the conditions for participating in this study?

In order to participate in this research, you must be affiliated to or benefit from a social security scheme. However, your participation in this research will not result in any additional costs for you compared to those incurred in the usual care.

Number of patients planned and duration of research?

This research will last 21 months with a 20-month recruitment period to include 266 patients.

What data is collected for the research?

The medical data collected during this study will be processed in a computerised, coded and confidential manner. The main data collected will be anthropometric data (age, weight, height, etc.), related to medical history, nutritional status, biological check-ups, and the results of check-ups by rehabilitation professionals (physiotherapists, dieticians, EAPA). No information bearing your name will be provided to anyone except the doctor in charge of the study and authorised personnel. All data collected will be confidential and coded and analysed in the

clinical research office of the Forcilles-Fondation Cognacq-Jay Hospital, the research sponsor. The identification list (correspondence between your study code and your identity) will be kept strictly confidential.
In accordance with the regulations in force, the data will be kept until the final research report is produced and then archived for 15 years.
The data controller is the promoter, Hôpital Forcilles-Fondation Cognacq-Jay, route de Servon 77150 Férolles-Attilly.

Legal basis for data processing

The processing of the data is based on the legitimate interests of the controller, Article 6 paragraph 1 point f, read in conjunction with the necessity of the processing for scientific research purposes, Article 9 paragraph 2 point j, of the European Regulation N° 2016/679 (General Data Protection Regulation, GDPR).

What are your rights?

Your participation in this research is **entirely free and voluntary**. You have the right not to participate in this research.
You cannot be included in an interventional research protocol with minimal risks and constraints without having been informed beforehand. Your doctor must provide you with all the necessary explanations concerning this research, which must comply with the provisions of Article 13 of European Regulation No. 2016/679 (General Data Protection Regulation, GDPR). In accordance with article L.1122-1 of the French Public Health Code, the entire research file has been submitted to the Comité de Protection des Personnes NORD OUEST III which issued a favourable opinion on xx/xx/xxxx.
The Forcilles-Fondation Cognacq-Jay hospital has taken out insurance under contract no. 163607 guaranteeing its civil liability and that of all those involved with the company SHAM.
You can stop participating in the research at any time without justification. This will not affect the quality of the care and treatment provided to you or your relationship with your doctor. The data collected until you withdraw your consent will be used unless you expressly request it. Indeed, in accordance with Article 17 of the GDPR, you have the right to request the deletion of your data already collected. The withdrawal of your consent and the agreement to use or not your previously collected data will be traced in your medical file.

In accordance with the provisions of Articles 15 and 16 of Regulation (EU) 2016/679 of 27 April 2016 (General Data Protection Regulation), you have a right of access, rectification, erasure or restriction of processing. You can find out more about your rights by consulting the CNIL website page https://www.cnil.fr/fr/reglement-europeen-protection-donnees/chapitre3.

In accordance with the provisions of Article 21 of the RGPD, you also have the right to object to the transmission of data likely to be used in the context of this research and to be processed. Your request must be addressed to the Data Protection Officer of the Cognacq-Jay Foundation, either by e-mail to the address dpo@cognacq-jay.fr or by post to the address: Hôpital Forcilles-Fondation Cognacq-Jay, Délégué à la Protection des Données, route de Servon 77150 Férolles-Attilly. You also have the right to lodge a complaint with the Commission Nationale de l'Informatique et des Libertés - CNIL (French personal data control authority, website: www.cnil.fr).
In application of the provisions of article L. 1111-7 of the Public Health Code, you may also access all of your medical data directly or through a doctor of your choice.
Your medical file will remain confidential and can only be consulted under the responsibility of the doctor in charge of your treatment, as well as by the health authorities and by persons duly mandated by the Forcilles-Fondation Cognacq-Jay hospital for research and subject to professional secrecy.
If, after having read all this information and discussed all aspects with the doctor in charge of the research, you have had sufficient time to reflect on your decision and you decide to participate in this research, the research information and your oral consent will be notified and dated in your medical file.

The agreement to participate in this research is free and voluntary.
You may refuse or withdraw your consent at any time without explanation or prejudice.

Any questions?

Dr. _____ (tel. _____) is at your disposal for any further information you may require before and during the research.

18 List of investigators

LIST OF INVESTIGATORS			
FIRST NAME, LAST NAME	**ROLE**	**FUNCTION**	**CONTACT INFORMATION**
Ilham BENHARRATS	Principal investigator	Internist	ibenharrats@cognacq-jay.fr 01.60.64.61.78
Virginie COLELLA	Co-investigator	APA teacher	vcolella@cognacq-jay.fr
Aymeric LE NEINDRE	Co-investigator	Physiotherapist	aleneindre@cognacq-jay.fr
Carlos DIAZ LOPEZ	Co-investigator	Physiotherapist	clopez@cognacq-jay.fr
Salima KALLA	Co-investigator	Oncologist	skalla@cognacq-jay.fr
Leïla NAHAL	Co-investigator	Dietician	lnahal@cognacq-jay.fr
Mohand TAGZIRT	Co-investigator	Geriatrician	mtagzirt@cognacq-jay.fr
Cécile SERON	Co-investigator	Dietician	cseron@cognacq-jay.fr
Maxime CADORET	Co-investigator	Dietician	mcadoret@cognacq-jay.fr
Tom BARBOSA	Co-investigator	APA teacher	tbarbosa@cognacq-jay.fr
Caroline O'CONNELL	Co-investigator	Pneumologist	Co'connell@cognacq-jay.fr
Sophie VIDAL-JESSEL	Co-investigator	Diabetologist	svidaljessel@cognacq-jay.fr