The impact of pelvic joint stiffness on the fear of falling in hospitalized and institutionalized elderly subjects over 75 years of age. Study of a cohort of 100 patients (Acronym: RAAPC).

Sponsor Code: 294

RIPH-3 EVALUATION PROTOCOL

Version n°2 of *14/10/2021*

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HISTORY OF PROTOCOL UPDATES

VERSION	DATE	REASON FOR UPDATE

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LIST OF ABBREVIATIONS

DDL: Degree Of Freedom
EHPAD: Etablissement d'Hébergement pour Personnes Agées Dépendantes
FES-I: Falls Efficacy Scale International
GHSIF: Groupe Hospitalier Sud Ile-de-France
ICC: Intraclass Correlation Coefficient
JS: Joint Stiffness
NA: Not Applicable
RA: Rheumatoid Arthritis
ProFaNE: Prevention of Falls Network Europe

CONTENTS

1. ABSTRACT

The impact of pelvic joint stiffness on the fear of falling in subjects over 75 years of age, hospitalized or in an institution. Study of a cohort of 100 patients.

JS (joint stiffness associated with fear of falling)

Background:

Purpose:

Fear of falling is one of the most concern in geriatric medicine. It could modify the daily activities of the elderly and create secondary troubles like sarcopenia, depression, it decreases the quality of life for this population.

Abstract: Fear of falling is defined as the enduring preoccupation with falling, leading the person to avoid activities that they are capable of doing. It modifies its behavior and affects its quality of life, its well-being and increases the risk of developing pathologies linked to the lack of physical activities. Joint stiffness is a major disorder in the elderly linked to bone and joint aging, but also to lack of mobilization. The pelvic girdle is the mechanical structure at the center of the balance and gait systems. The lack of amplitude of the joints that compose it could induce a fear of falling.

This study seeks to highlight whether there is an association between the fear of falling and the lack of amplitude of the different joints of the pelvic girdle.

Primary outcome:

Highlight a significant positive association between the Schober index (quantitative) and / or hip flexion goniometry (quantitative) and / or hip extension goniometry (quantitative) with the FES-I score (qualitative 2 groups).

Secondary outcomes: - Validity of 3 FES-I categories according to anthropometric measurements

- - Evaluation of the linearity of the association
- - Assessment of the strength of association
- - Impact of cofactors collected on FES-I (polypharmacy, history of fall)

Study design: description of the main features of the research according to type of research

Eligibility criteria:

inclusion criteria:

- over 75 years old
- Ability to understand and answer a questionnaire in French
- Ability to stand up
- Patient from the Melun hospital (santé pole center+ nursing home of the GHSIF)
- Affiliated with a social security scheme

exclusion criteria:

- mental disorders, lumbar surgery

Interventions: Procedure: Study of a cohort of 100 patients

1 / evaluation of the fear of falling using an FES-I questionnaire, distribution of subjects according to the score into 3 groups (16-19: little concerned by the fear of falling, 20-27 moderately concerned, 28-64 very concerned by fear of falling)

2 / evaluation of lumbar articular mobility by the schober index, coxofemoral by hip goniometry in flexion and extension (no evaluation of other amplitudes because lack of abduction / abduction / external and internal rotation of the hip remain functional in walking and the balance)

Number of subjects: 100

Statistical analysis: Pearson and Mann Whitney Correlation Test Chi-2 Test

2. SCIENTIFIC JUSTIFICATION

2.1. CURRENT STATE OF KNOWLEDGE

2.1.1. PATHOLOGY

Fear of falling is defined as the enduring preoccupation with falling, leading the person to avoid activities he/she is capable of performing. (Tinetti & Powell, 1993)[1]. Anxiety linked to the fear of falling can have a significant impact on a person's activities and independence, and can lead to the deconditioning of their functional capacities. The subject feels his or her fragility and dependence on others, and becomes aware of his or her ageing.

2.1.2. REFERENCE STRATEGIES/PROCEDURES

The risk factors for fear of falling are essentially psychological, age-related and social. Management of the fear of falling responds to the origin of the problem, but remains multidimensional and multidisciplinary. The aim is to reassure the sufferer, while encouraging him or her to participate as fully as possible in everyday activities. By combining behavioral and cognitive therapies with physiotherapy, we can improve the symptomatology and prognosis of elderly sufferers.

The physical component is not well identified as a risk factor in elderly people afraid of falling. However, studies have shown that physical exercise based on gentle muscle strengthening and proprioception, such as Tai Chi, helps to reduce the fear of falling in the short term (Kendrick & al, 2014) [(2)] (Taggart, 2002)[3]. Fessel and Nevitt also found that fear of falling motivated many elderly people with Rheumatoid Arthritis (RA) to avoid or modify specific activities (Fessel & Newitt, 2005)[4].

2.1.3. DESCRIPTION AND RATIONALE OF THE STUDY POPULATION

The aim of this study is to determine whether the intensity of joint stiffness is associated with high apprehension of falling in elderly patients.

We chose to carry out the study in this population because: hospitalized patients or residents of Residential Care Facility for Dependent Elderly People (EHPAD in French) are at greater risk of fear of falling.

2.1.4. JUSTIFICATION FOR THE DURATION OF THE STUDY.

A retrospective analysis of observational data carried out on a sample drawn from a similar population enabled us to calculate the minimum number of subjects required to demonstrate a statistically significant association between the reference test and at least one of the variables studied. It is worth noting that 100 patients are required to reject the null hypothesis of the primary objective with 90% power and 5% risk.
Given the number of geriatric patients at the Southern Ile-de-France Hospital Group (GHSIF), a 6-month period is planned to reach the number of patients required for this study.

Once a patient is included in the study, the total duration of his/her participation is 30 minutes.
Inclusion and evaluation of patients is carried out progressively over the course of the study.

The total duration of the study is therefore estimated at 6 months.

2.2. Research hypotheses

The elderly frequently present stiffness in the various joints of the pelvic girdle. These limitations in pelvic amplitude, caused by muscular or rheumatic pathologies, induce a reduction in proprioceptive response, leading to increased gait or balance disorders, and possibly a fear of falling.
Is the intensity of joint stiffness associated with a heightened fear of falling in elderly patients?

2.3. JUSTIFICATION OF METHODOLOGICAL CHOICES

In our study, we aim to assess whether there is an association between joint stiffness (uncontrollable exposure) and fear of falling (uncontrollable event). The appropriate study design is therefore that of a prospective cohort with secondary analysis of subgroups within the cohort.

The FES-I is a reference test in geriatrics for assessing fear of falling. Its validity is recognized in geriatrics and for patients with minor cognitive impairment.

Goniometry and the Schober index provide a reliable assessment of joint mobility, with no lack of specificity or sensitivity compared with other joint mobility tests.

To measure the association between fear of falling and joint stiffness, we decided to record them at an instant T (inclusion). These variables may fluctuate within a patient, but it is not the evolution of these parameters that we wish to evaluate, only the implication of one on the other.

2.4. BENEFIT/RISK RATIO

The benefits of this study:

- Identify people at risk of fear of falling
- Identify a new risk factor for fear of falling, in order to adapt prevention measures.

Risk

There are no risks involved in this study.

2.5. EXPECTED BENEFITS

Fear of falling is a major concern in elderly patients. The risk factors identified are social, psychological, linked to a history of falls or the use of medication. This fear restricts physical activity and reduces quality of life.
The pelvic girdle is central to our postural balance. Its suppleness guarantees the proper adaptation of our static and dynamic body schema.

Aging can lead to osteoarticular stiffness and connective tissue fibrosis, a reduction in range of motion and thus a loss of proprioceptive adaptation of the pelvic girdle. By identifying joint stiffness as a risk factor for fear of falling, we can treat this factor and influence the fear of falling. Elderly patients regain confidence, their fear of falling diminishes and they are encouraged to resume physical activity gradually and at their own pace.

3. RESEARCH OBJECTIVES

3.1. MAIN OBJECTIVE

To demonstrate a significant association between the Schober index (quantitative) and/or hip goniometry in flexion (quantitative) and/or hip goniometry in extension (quantitative) with the FES-I score (qualitative 2 groups).

3.2. SECONDARY OBJECTIVES

- Validity of 3 FES-I categories according to anthropometric measurements
- Assessment of linearity of association
- Assessment of strength of association
- Impact of cofactors collected on FES-I (polymedication, history of falls).

4. EVALUATION CRITERIA

4.1. MAIN EVALUATION CRITERION

FES-I questionnaire

This questionnaire comprises sixteen items. It is an improved version of the Fall Efficacy Scale (FES) proposed by Tinetti (18). The FES-I was developed by the Prevention of Falls Network Europe (ProFaNE). It is available on the ProFaNE website. A version of the FES-I scale has been translated into French. The questionnaire works as follows: for each proposition (16 in all), respondents are asked to rate their level of anxiety when imagining themselves carrying out the corresponding action. For each item, the respondent's level of concern is rated on a scale from 1 to 4, with the following correspondences:
1 not at all worried;
2 a little worried;
3 quite worried;
4 very worried.
The final score for this test is therefore between 16 and 64. The higher the score, the greater the fear of falling. The cut-point for this questionnaire, defining a high level of apprehension about falling, is set for scores scores greater than or equal to 28, according to research by (Delbaere et al, 2010)[5]

Hip goniometry

Hip goniometry: expressed in degrees, measures hip joint amplitude in active flexion and extension using a goniometer. The measurement is taken standing up. We evaluate one hip, the one that appears most mobile to the patient. With the goniometer at the level of the greater trochanter, we ask the patient to actively flex the hip, knee bent, checking that the lumbar vertebrae are not engaged. Same procedure on the same leg for straight-leg hip extension.

Modified Schober index

Modified Schober Index: This test is used to identify patients with ankylosing spondylitis (Macrae & Wright, 1969)6 and assesses lumbar joint mobility in flexion. Subsequent studies have shown the test to be reliable and reproducible (Koppenhaver et *al*., 2011)[7], (Malanga et *al.*, 2005)[8].
• When the patient is standing, a first mark is made at the sacro-lumbar junction or between the posterior-superior iliac spines;
• a second mark is made 10 cm above the sacro-lumbar junction;
• a third mark is made 5 cm below the sacro-lumbar junction;
• a measuring tape is stretched between the three marks and the distance between the first and third marks is recorded, in neutral position and at maximum flexion of the lumbar spine;
• a deviation of less than 5 cm is considered pathological.
Measurements of mobility in extension and lateral flexion are also available, since ankylosing spondylitis limits mobility in all planes of motion. (Moll et al., 1971)[9]. Sensitivity
0.25 to 0.30 Specificity 0.86 to 0.95 Intra-examiner ICC 0.87 (good correlation) Inter-examiner ICC
0.79 (moderate correlation).

4.2. Secondary endpoints

- Number of current drug treatments
- History of falls
- Age

5. METHODOLOGY / RESEARCH DESIGN

5.1. RESEARCH DESIGN

Prospective multicenter cohort study

Recruiting centers: Geriatrics Center of Southern Ile-de-France Hospital Group
- Melun Hospital
- EHPAD Melun
- EHPAD Brie-Comte-Robert

6. STUDY POPULATION / ELIGIBILITY CRITERIA

6.1. INCLUSION CRITERIA

- Patients over 75 years of age cared for by the geriatrics unit of Southern Ile-de-France Hospital Group (either hospitalized or institutionalized).
- Patient able to understand a questionnaire in French
- Patient able to answer a questionnaire in French
- Patient able to stand up
- Patient able to consent

6.2. NON-INCLUSION CRITERIA

- Patient who has had lumbar surgery at some time in his or her life
- Patient under guardianship
- Patient under guardianship
- Patient opposition
- Patient with cognitive disorders assessed during hospitalization

6.3. RECRUITMENT PROCEDURES

Patients are recruited during a follow-up consultation during their hospitalization, or during their stay for EHPAD patients, at the suggestion of the therapeutic team, from among patients cared for by Southern Ile-de-France Hospital Group geriatrics unit.

Patients will be informed individually and given an information note to read. If they so wish, they will be offered a two-day cooling-off period, and if they agree to take part (non-objection) they will be able to ask any questions they may have before deciding to take part in the study. Inclusion and non-inclusion criteria will then be checked in the medical file (age, existence of cognitive disorders, etc.).

7. ASSOCIATED ACTS/TREATMENTS/PROCEDURES

7.1. Authorized associated acts/treatments/procedures

NA

7.2. Associated acts/treatments/procedures prohibited

NA

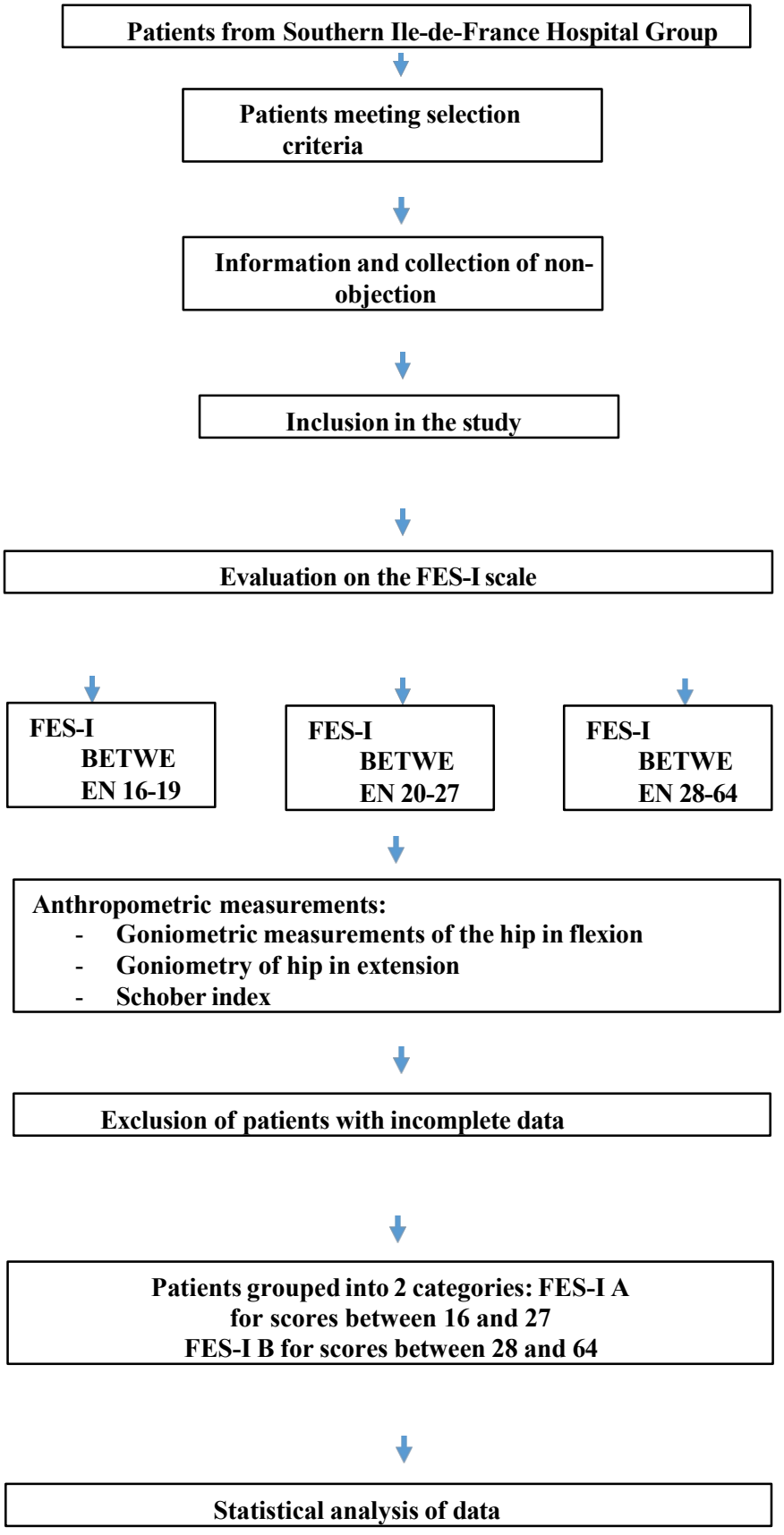
7.3. CARE-RESEARCH DISTINCTION

MANAGEMENT COMPARISON TABLE

Procedures and treatments	Care-related procedures	Research-related acts
Hospitalization	X	
FES-I questionnaire		X
Hip goniometry		X
Schober index		X

8. RESEARCH PROCESS

The diagram below shows the research process.


Patients from Southern Ile-de-France Hospital Group
Patients meeting selection criteria
Information and collection of non-objection
Inclusion in the study
Evaluation on the FES-I scale
FES-I BETWEEN 16-19
FES-I BETWEEN 20-27
FES-I BETWEEN 28-64
Anthropometric measurements:
- Goniometric measurements of the hip in flexion
- Goniometry of hip in extension
- Schober index
Exclusion of patients with incomplete data
Patients grouped into 2 categories: FES-I A for scores between 16 and 27
FES-I B for scores between 28 and 64
Statistical analysis of data

8.1. Research schedule

- Start of inclusion: September 2021
- Length of inclusion period: 6 months
- Duration of each patient's participation: 30 minutes
- Total duration of research: 6 months, can be stopped early as soon as the required number of patients of patients required

8.2. Summary table of patient follow-up

There is no patient follow-up for this study.

Summary table of research phases

	Inclusion T 0
Information	✓
No opposition	✓
Questionnaire	✓
Clinical examination	✓

8.3. INFORMATION FOR PERSONS CONCERNED

In accordance with article L1122-1 of the French Public Health Code, prior to the performance of research involving the human person, information is provided to the person participating in the research by the investigator or by a physician representing the investigator. When the investigator is a qualified person, this information is provided by that person or by another qualified person representing him or her.

In accordance with article L1122-1-1 of the French Public Health Code, no research mentioned in 3° of the same article L. 1121-1 may be carried out on a person if that person has objected to it.

Before any research-related procedures or examinations are carried out, the investigator must inform the patient.

Patient information will be provided during the consultation. Patients will be informed directly by the investigator, and will have the opportunity to ask questions and object to their participation in the study.

8.4. Visit

The study will take place during the patient's consultation, at which time the study will be proposed to the patient.

During the consultation and before any research-related examination, the investigator proposes that the patient to take part in this research and informs him/her of the following in particular:

- the objective, methodology and duration of the study
- Expected benefits
- The computerized processing of data concerning the patient that will be collected in the course of the research, and the patient's rights of access, opposition and rectification.

A copy of the information document is given to the patient prior to participation in the research.

During this visit, the investigator also checks the patient's eligibility criteria. If the patient agrees to participate, he or she gives oral consent during the consultation.

This information is recorded in the patient's medical record.
The non-opposition of the patient will be recorded in the patient's medical file by the investigator or qualified qualified person.

Any amendment that modifies patient management or the benefits, risks and constraints of the research will be the subject of a new information document. The procedure for informing the persons concerned is the same as that described above.

8.5. Randomization

NA

8.6. End-of-research visit

There is only one end-of-study visit.

8.7. Special monitoring procedures

NA

8.8. Research termination rules

For this study, the stopping rules will be :

- Inability or refusal of the included patient to perform one of the measurements (hip goniometry or Schober index measurement).
- Incomplete FES-I questionnaire
- Occurrence of a non-inclusion criterion

9. STATISTICAL ASPECTS

Main objective

The null hypothesis H0 for the primary objective is the absence of a positive association between Schober index (quantitative) and/or hip goniometry in flexion (quantitative) and/or hip goniometry in extension (quantitative) with the FES-I score (qualitative 2 groups).

To reject H0, we group 2 FES-I categories (FES-I A: FES-I measured 16-19 "little concerned" and 20- 17 "moderately concerned") and compare them with the 3rd FES-I category (FES-I B: FES-I measured 28-64 "very concerned"). The values of the 3 anthropometric measurements will be compared between the FES-I A and FES-I B groups by Mann-Whitney tests.

Secondary objectives and analysis :

- Validity of 3 FES-I categories according to anthropometric measures: simple descriptive analysis; a chi-2 test may be performed in the absence of ordinal categorization.

- Assessment of the linearity of the association: linear logistic regression tests will be performed with FES-I values and each anthropometric variable (β-slope test, $p< 0.05$)

- Assessment of strength of association: Spearman correlation tests will be performed between the value of of FES-I and each of the 3 anthropometric variables (ρ, R^2, $p< 0.05$)

- Impact of cofactors collected on FES-I: a univariate analysis will be performed between FES-I A and FES-I B for the variables "number of drug treatments" and age (Mann Whitney test, $p < 0.05$) and for antecedent falls (Fischer exact test, $p < 0.05$). In the event of a significant difference in rates of previous falls between FES-I A and FES-I B groups, a subgroup analysis (patients without and with previous falls) between the 3 variables and FES-I A and FES-I B groups (Mann-Whitney test, corrected $p < 0.03$) will be carried out according to the numbers observed.

10. RISKS AND VIGILANCE

This is a non-interventional study.

Adverse events observed in patients taking part in the research will be reported by the investigators in accordance with the systems put in place as part of healthcare vigilance.

11. ACCESS RIGHTS TO DATA AND SOURCE DOCUMENTS

11.1. ACCESS TO DATA

The Sponsor is responsible for obtaining the agreement of all parties involved in the research to ensure direct access to all research sites, source data, source documents and reports for quality control and audit purposes.
The persons directing and supervising the research will make the documents and individual data strictly necessary for monitoring, quality control and auditing of the research available to persons with access to these documents in accordance with the legislative and regulatory provisions in force.

11.2. SOURCE DATA

Any original document or object that can be used to prove the existence or accuracy of data or facts recorded in the course of research is defined as a source document.

For the purposes of this study, the source documents will be:

- Patient medical records
- Patient observation notebooks

11.3. DATA CONFIDENTIALITY

In accordance with current legislation, persons with direct access to source data will take all necessary precautions to ensure the confidentiality of information relating to the research, to the persons involved, and in particular to their identity, as well as to the results obtained. These persons, as well as the persons directing and supervising the research, are bound by professional secrecy.

During the research or at its conclusion, the data collected on the persons involved and transmitted to the promoter by the persons directing and supervising the research (or any other specialist) will be codified. Under no circumstances should the names or addresses of the persons concerned appear in plain text.

For coding purposes, only the first letters of the patient's surname and first name will be recorded, accompanied by a coded number specific to the research project, indicating the order of patient inclusion.

The promoter will ensure that each person taking part in the research has been informed of the access to individual data
strictly necessary for the quality control of the research.

12. QUALITY CONTROL AND ASSURANCE

12.1. DATA COLLECTION INSTRUCTIONS

All information required by the protocol must be recorded in the observation notebooks, and any missing data must be explained. Data should be collected as they are obtained, and transcribed neatly and legibly into the notebooks.
Erroneous data recorded in the observation notebooks should be clearly crossed out, and the new data should be copied next to the crossed-out information, accompanied by initials, date and, where appropriate, a justification by the person directing and supervising the research, or the authorized person who made the correction.

For the purposes of this study, data will be collected on a paper observation notebook.
Data collection will be carried out by: the investigator at each site
Data will be collected during the patient's stay and hospitalization.
The data collected in this study will be:

- Age
- gender
- History of falls
- Number of current drug treatments
- FES-I questionnaire score
- Hip goniometry in flexion
- Hip goniometry in extension
- Lumbar schober index

The data used in this study will come from: patients' medical records, the FES-I questionnaire and the measurements taken.
In order to carry out this study, pseudonymized data will be transmitted to the promotion unit of the clinical research unit

12.2. IDENTIFICATION OF DATA COLLECTED DIRECTLY IN THE CASE REPORT FORMS, WHICH WILL BE CONSIDERED AS SOURCE DATA

The observation book data used as source data are:

- FES-I score
- Schober index
- Hip goniometry in flexion
- Hip goniometry in extension

12.3. DATA CIRCUIT

For each patient, data from the medical record and consultation (clinical examination and questionnaire) are collated in the observation notebook.

Data from the observation book is pseudonymized and entered into the database. The database is

frozen and the data analyzed statistically.

The results of this study will first be presented in a thesis/internship report.

12.4. RESEARCH FOLLOW-UP

The clinical research unit at Melun Hospital will monitor the research. It will work with the research supervisor to check the content of the observation notebooks against the data entered in the database.

12.5. QUALITY CONTROL

Qualification of participants

The coordinating investigator, the qualified person or the person in charge of the research ensures that those involved in the research are qualified for the tasks they perform.

The persons responsible for quality control will take all necessary precautions to ensure the confidentiality of information relating to the research, to the persons involved, and in particular to their identity, as well as to the results obtained.

12.6. AUDIT AND INSPECTION

An audit may be carried out at any time by persons appointed by the sponsor, who are independent of those in charge of the research. Its purpose is to ensure the quality of the research, the validity of its results and compliance with the law and regulations in force.

The persons directing and supervising the research agree to comply with the requirements of the sponsor and the competent authority with regard to an audit or inspection of the research.

The audit may apply to all stages of the research, from protocol development to publication of results publication of results and the classification of data used or produced as part of the research.

12.7. DATA OWNERSHIP

The sponsor is the owner of the data and no use or transmission to a third party may be made to a third party without the sponsor's prior knowledge and consent.

13. ETHICAL AND REGULATORY CONSIDERATIONS

13.1. COMPLIANCE WITH REFERENCE TEXTS

The sponsor and the investigators undertake that this research will be carried out in compliance with the law, as well as in accordance with Good Clinical Practice and the latest version of the Declaration of Helsinki.

The research will be conducted in accordance with the present protocol. With the exception of emergency situations requiring the implementation of specific therapeutic acts, the persons directing and supervising the research undertake to comply with the protocol in all respects.

This research has received the favorable opinion of the Committee for the Protection of Persons (CPP) of *CPP's name on date.*

The sponsor will send the CPP's opinion and a summary to the National Agency for Medicines Safety (ANSM) for information.

The data recorded in the course of this research will be processed electronically within Southern Ile-de-France Hospital Group in compliance with the French Data Protection Act n°78-17 of January 6, 1978 and the European Regulation 2016/679 General Data Protection Regulation - RGPD.

This research is a RIPH3 using personal data under the responsibility of GHSIF. It is of public interest insofar as it contributes to research, studies, evaluation and innovation in the fields of health and medico-social care, and insofar as the information and collection of the non-objection of persons is prior to their inclusion.

Computerized processing of personal data will comply with the Reference Methodology for the processing of personal data in the context of health research in the health field" (MR-003).

The research promoter has signed a commitment to comply with this "Reference Methodology".

13.2. PROTOCOL AMENDMENT

Any substantial modification, i.e. any modification likely to have a significant impact on the protection of individuals, on the conditions of validity and on the results of the research, on the interpretation of the scientific documents supporting the conduct of the research, or on the methods of conducting the research, is the subject of a written amendment submitted to the Sponsor, who must obtain a favorable opinion from the CPP prior to its implementation.
Non-substantial modifications, i.e. those having no significant impact on any aspect of the any aspect of the research, are communicated to the CPP for information purposes.
All amendments to the protocol must be brought to the attention of all healthcare professionals taking part in the research, who undertake to abide by its content.

If necessary, the information memorandum and the procedures for obtaining non-opposition may be revised, particularly in the event of substantial modification.

13.3. THE INVESTIGATOR'S RESPONSIBILITIES TOWARDS THE SPONSOR

The coordinating investigator or qualified person undertakes to provide the sponsor with information concerning the inclusion of patients in the study.

13.4. THE FINAL RESEARCH REPORT

The final report on research involving the human body, as referred to in article R1123-67 of the CSP, is drawn up and signed by the sponsor and all the investigators, or failing this, by the coordinating investigator. In the latter case, all investigators are informed of the results of the research by the coordinating investigator or the sponsor. This report is made available to the competent authority (ANSM). A summary of the report, drawn up in accordance with the competent authority's reference plan, must be sent to the competent authority within one year of the end of the research, corresponding to the end of the participation of the last person involved in the research.

After the end of the research, if the sponsor becomes aware of any new fact likely to have a significant impact on the safety of the persons who took part in the research, he must inform the competent authority without delay, and specify the appropriate measures he intends to put in place. If the competent authority considers the planned measures to be insufficient, it may require the sponsor to take appropriate measures.

14. DATA PROCESSING AND STORAGE OF RESEARCH DOCUMENTS AND DATA

14.1. DATA PROCESSING

Data will be entered in a paper observation book and re-read when comparing the data in the observation book with the data entered in the database.

- Statistical analysis will be carried out by the biostatistician in the clinical research unit at Melun hospital.
- Prism 6 software (GraphPad Software Inc®, San Diego, CA, USA).
- Data will be stored in Microsoft Excel files, secured by password and stored off- network.
- Data freeze/unfreeze process: only the principal investigator and the statistician have access to the database; only the principal investigator has access to the patient identity/anonymity number correspondence table.
- Data backup procedures: data are backed up daily in accordance with the computer system procedure.

14.2. RETENTION OF RESEARCH DOCUMENTS

The following documents relating to this research are archived in accordance with Good Clinical Practice and current regulations for a period of 15 years following the end of the research:

- By the investigator:
  - Protocol and any amendments to the protocol
  - Observation notebooks
  - Participants' source files
  - All other documents and correspondence relating to the research.

All these documents are the investigator's responsibility for the duration of the archiving period.

- By the sponsor:
  - Protocol and any amendments to the protocol
  - Original case report forms
  - All other documents and correspondence relating to the research.

All these documents are the responsibility of the Sponsor during the regulatory archiving period.

They may not be moved or destroyed without the agreement of the Sponsor. At the end of the regulatory archiving period, the Promoter will be consulted for destruction and will give his written agreement. All data, documents and reports may be subject to audit or inspection.

15. FINANCING

All expenses incurred by this study will be covered by Southern Ile-de-France Hospital Group.

16. PUBLICATION RULES

16.1. SCIENTIFIC COMMUNICATIONS

Data analysis is carried out by Southern Ile-de-France Hospital Group. This analysis gives rise to a written report which may be used in the preparation of one or more publications.

Any written or oral communication of research results must receive prior approval from the coordinating investigator.

The publication of the main results mentions the Southern Ile-de-France Hospital Group, the investigators who included patients in the research, the methodologist and the scientific manager.

International rules for writing and publication (Vancouver Convention, February Vancouver Convention, February 2006).

The results of this study may be published, presented at congresses, and used in internship reports and dissertations.

16.2. COMMUNICATION OF RESULTS TO PATIENTS

In accordance with French law n°2002-303 of March 4, 2002, patients are informed, at their request, of the overall results of the research.

16.3. TRANSFER OF DATA

Southern Ile-de-France Hospital Group is responsible for data collection and management. The conditions of transfer of all or part of the research database are decided by Southern Ile-de-France Hospital Group and are the subject of a written contract.

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