Information note for participation in research

"Pilot study on fall prediction"

in motor imagery »

Short title: " FallMI "

Investigator
Name : ……
Establishment : CHD Vendée, La Roche sur Yon

Institution responsible for research and data processing
CHD of La Roche sur Yon - Boulevard Stéphane Moreau, 85925 La Roche sur Yon Cedex 9
Clinical Research Unit Secretariat: 0 2 51 44 65 72

The Data Protection Officer (DPO) of the Vendée Departmental Hospital Center (CHD Vendée)
CHD Vendée - Information System Department
Boulevard Stéphane MOREAU - 85925 La Roche sur Yon Cedex 9
Email: dpo@chd-vendee.fr Telephone: 02 51 44 65 72

This document is read and given to patients. A printed copy is given to them (after oral agreement). A copy is kept outside the medical file with the study documents.

Madam, Sir,

You have been invited to participate in a clinical study called **FallMI.** The CHD Vendée in La Roche sur Yon is the sponsor of this study, is responsible for it and ensures its organization.
Before deciding to participate in this study, it is important for you to understand its purpose and implications. Please take the time to carefully read the following information and discuss it with your family and friends. If anything is unclear or you require further information, please do not hesitate to speak with the healthcare professional who is offering you the study.

Your participation in this research is entirely voluntary, and you have the right to refuse to participate. In that case, you will continue to receive the best possible medical care, in accordance with current knowledge.

1- OBJECTIVE OF THE STUDY

You were monitored as part of a screening for bone fragility called osteoporosis.

Osteoporosis is a bone disease characterized by both a decrease in bone density and changes in its microarchitecture. Bones become more fragile and less resistant, and consequently, the risk of fractures increases (fractures of the hip, wrist, vertebrae, etc.). This bone fragility can lead to spontaneous fractures and therefore falls.

Following your screening, it was found that you have one or more risk factors for osteoporosis.

Therefore, as part of your care, several examinations were carried out, including the walking test called "Time Up and Go".

This timed clinical test involves standing up from a chair with armrests, walking 3 meters, and returning to a seat at your comfortable pace. You will need to complete it first by actually doing it (performed TUG), and then by imagining yourself doing it while seated in your chair (imagined TUG).

The aim of this study is to identify, within a population with risk factors for osteoporosis, patients who may also exhibit impaired motor skills, as evidenced by an "abnormal" gait test result and/or a significant difference between the actual and imagined gait test results. Our hypothesis is that the results of both actual and imagined gait tests could be used to predict falls.

2- STUDY PROCESS

If you agree to participate, we ask that you provide us with the contact details of your attending physician.
This will be consulted in 6 months and in 1 year to gather information on any falls that may have occurred during this period. If it is impossible to contact your primary care physician, you will be contacted as a second option.

This study will take place over one year and will involve approximately 150 patients who, like you, will benefit from osteoporosis screening at the CHD Vendée and for whom one or more risk factors for osteoporosis have been identified.

No compensation is provided for your participation in the study. All costs incurred by the protocol are covered by the institution responsible for the research (CHD Vendée).

3- POTENTIAL RISKS OF THE STUDY

This research presents no additional risk compared to normal care and the latter will not be changed regardless of your decision.

4- POTENTIAL BENEFITS OF THE STUDY

There is no direct benefit for you in participating in the study, but the results of the study may be useful to other patients in the future because if the walking tests are indeed predictive of falls, it will then be possible to put in place a preventive strategy for the patients concerned.

The results of this study will not provide information relevant to your specific health. They will contribute to the development of knowledge in the field of osteoporosis and fall prevention.

5- VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary.

You are free to refuse to participate and to terminate your participation in the study at any time, without incurring any liability or prejudice as a result and without this having any consequences on the quality of care that will be provided to you.
In this case, you must inform the investigator of your decision.
In the event that you withdraw your consent, we will process your personal data already collected electronically unless you object in writing.

During the study, you will be notified by your investigator if any new facts could affect your willingness to participate in the study.

The Health Authorities, the investigator, or the sponsor may decide to terminate your participation in the study at any time without your prior consent. If this were to happen, you would be notified and the reasons would be explained to you.

6- OBTAINING ADDITIONAL INFORMATION

If you wish, Mr. Thomas RULLEAU, whom you can contact at the following telephone number 02 51 44 65 72 (clinical research secretariat), will be able to answer any questions you may have regarding the **FallMI study at any time**.

At the end of the study, and at your request, you can be informed of the overall results of the research by your investigator.

7- CONFIDENTIALITY AND USE OF MEDICAL DATA

As part of the non-interventional research in which CHD Vendée and Mr. Thomas RULLEAU are offering you the opportunity to participate, your personal data will be processed to allow us to analyze the results of the research in relation to its objective, which has been presented to you.

To this end, the medical data collected, including any questionnaires, and data relating to your lifestyle habits will be transmitted to the Research Sponsor or to persons or companies acting on its behalf in France.
This data will be identified by a code number and your initials [*first letter of last name and first letter of first name*] and will be kept for 15 years (from the date of completion of studies).

The staff involved in the study are bound by professional secrecy, just like your attending physician.

This data may also, under conditions ensuring its confidentiality, be transmitted to French or foreign health authorities, or to other entities of the CHD Vendée.

In accordance with the provisions of the law relating to information technology, files and freedoms (law of 6 January 1978), you have a right of access (possibility of obtaining a free copy), rectification, deletion, and a right to object to the transmission of data covered by professional secrecy that may be used in the context of this research and processed.
These rights are exercised with the doctor who is treating you as part of the research and who knows your identity.
However, all data collected prior to the withdrawal of consent may not be erased and may continue to be processed under the conditions provided for by the research.

You can also access all your medical data directly or through a doctor of your choice, in accordance with the provisions of Article L 1111-7 of the Code ofla Santé Publique.

You also have the right to lodge a complaint with a data protection supervisory authority (contact details below):

National Commission for Information Technology and Freedoms (CNIL)
3 Place de Fontenoy
TSA 80715
75334 PARIS Cedex 07
Telephone: 01 53 73 22 22

Any new information that arises during the course of the study and that may change your decision to participate in this study will be communicated to you as soon as possible.

8- FAVORABLE OPINION FROM THE CPP

In accordance with Law relating to public health policy, the Committee for the Protection of Persons of Rouen studied this research project and issued a favorable opinion for its implementation on 27/03/2019.

9- ANSM INFORMATION

In accordance with Law relating to public health policy, the ANSM was informed of the implementation of this project on April 25, 2019.

If you agree to participate in this study, please inform your doctor verbally.
You are keeping this newsletter.

Patient's Name/Surname:…….
Date of birth : …../……/……

Name/Surname of the person who provided the information:…….
Date of information delivery: …../……/……

I, the undersigned, attest that the patient received information regarding the **FallMI research protocol,** and that he did not object to participating in the study, the collection and analysis of his data.

Signature of the person who provided the information and obtained the patient's non-opposition: