LABORATOIRES VICTHOM INC.

Consent form

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NCT05814471

Project title

Protocol for the clinical validation of a valgus knee brace for gonarthrosis

Project team

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Why do we give you this form?

We invite you to participate in a clinical trial of a knee orthosis for gonarthrosis in development. The aim of this brace is to compensate for certain biomechanical deficits without compromising comfort, while being easy to fit and fasten. We are looking for 10 participants for this purpose.

Gonarthrosis is a chronic joint pathology of the knee, resulting in wear of the joint surfaces, which can eventually lead to friction between the bones. This wear manifests itself in pain, particularly when weight-bearing. The aim of knee orthoses is to compensate for certain biomechanical deficits in patients. A multitude of joint arrangements are available to target specific biomechanical deficits. A constant challenge for orthosis manufacturers is to transmit the biomechanical effect of the orthosis to the patient. The desired effect requires a change in the forces applied inside the joint, but the orthosis cannot directly transmit the forces to the patient's bones due to its external nature. Customization of orthotics is essential to improve the transmission of biomechanical effects, as well as tolerance to them. Comfort, ease of fitting and effectiveness are essential components of a quality orthosis. With this in mind, Laboratoires Victhom Inc. would like to test its new knee brace attachment system.

The information provided is intended to help you understand exactly what is required so that you can decide whether or not to participate in this study. Please read the form carefully and ask any questions you may have before making your decision. Take all the time you need, and consult the people of your choice if necessary. Your participation should be entirely voluntary. If you decide not to take part in the study, you will not be penalized in any way. If you have any questions, please do not hesitate to contact

Marianne Lancelot/Catherine Lavoie/Élizabeth Lafrance, Orthotist-Prosthetist, TOPMED
Tel.: (418) 780-1301
E-mail: etudes@topmed.ca

Participant inclusion criteria:

- Be 18 years of age or older;
- Have worn an ODRA 2.0 orthosis for an average of several hours a day over the past 6 months

Participant exclusion criteria:

- People with wounds on the lower limbs.

Why are we doing this study?

Laboratoires Victhom Inc. was created with the aim of developing new orthoses for people suffering from various pathologies. The objectives of the project are to develop and create a new knee orthosis for gonarthrosis, and to validate its effectiveness against the following criteria:

- Controlling the symptoms of gonarthrosis
- Orthosis comfort for daily activities
- Easy to install
- Orthosis assessment

What do you need to do?

Summary of your participation

You will be asked to try out 2 different attachment systems for a new gonarthrosis knee . You are expected to participate in all sessions. The individual sessions are detailed as follows:

- 1 45-minute appointment for impression taking
- 1 meeting of 1h45 for orthosis delivery
- 1 renewable 14-day fitting period
- 3 trial sessions (2h for the first 2 and 1h for the last)
- 2 14-day trial periods

Explanation of your participation

- Impression meeting
    - 45-minute meeting at the balance clinic to take a digital impression of your leg and anthropometric measurements to produce your new knee brace
- Delivery meeting
    - 1h45 meeting at the Clinique équilibre to deliver the orthosis and make adjustments as needed to optimize your comfort. You'll be asked questions about your physical and psychological symptoms, as well as your satisfaction with your personal orthosis. Photos of your leg wearing the new brace will be taken . From this point on, you will be required to wear your new orthosis on a daily basis.
- Adjustment period

    - Following the adjustment meeting, a 14-day renewable adjustment period begins. Once this period has elapsed, Trial 1 will take place.
- Adjustment meeting(s)
    - Meeting of variable length (45 minutes maximum) at the balance clinic to make adjustments to the orthosis to optimize your comfort. This meeting can be scheduled **at your request** if you experience discomfort during the adjustment period. If an adjustment meeting is held, the 14-day adjustment period is renewed.
- Test meeting 1:
    - 2-hour meeting at TOPMED to begin the trial phase. You will be asked to answer questions about your physical and psychological symptoms, as well as to provide general information (gender, age, height, weight and information on knee brace use). In addition, you'll be asked questions about your satisfaction with the fastening system(s) and brace tested. Photos will be taken of your leg wearing the brace. You'll receive explanations about the brace-wearing diary you'll be asked to fill in during the trial period. A change in the fastening system may be made at this meeting.
- Trial period 1
    - 14-day period during which you must complete a daily orthosis wear diary. Completing the orthosis wear diary takes 5 to 10 minutes. The diary will detail total wearing time, as well as sitting time, physical and sporting activities performed during the day, the number of times the brace is removed and adjusted, any discomfort experienced and medication taken. You can contact TOPMED if you have any questions or comments during this period.
- Test meeting 2
    - 2-hour meeting at TOPMED to continue the trial phase. You will be asked questions about your physical and psychological symptoms. In addition, you will be asked questions about your satisfaction with the brace attachment systems tested. Photographs will be taken of your leg wearing the brace. A change of fastening system will be made at this meeting.
- Trial period 2
    - 14-day period during which you must complete a daily orthosis wear diary. Completing the orthosis wear diary takes 5 to 10 minutes. The diary will detail total wearing time, as well as sitting time, physical and sporting activities performed during the day, the number of times the brace is removed and adjusted, any discomfort experienced and medication taken. You can contact TOPMED if you have any questions or comments during this period.
- Test meeting 3
    - 1-hour meeting at TOPMED to begin the trial phase. You'll be asked to answer questions about your physical and psychological symptoms, and about painting the brace. You will also be asked questions about your satisfaction with the brace systems tested, and about your orthotic preferences. Photos will be taken of your leg wearing the brace. The brace will be collected at this meeting.

Possible disadvantages and advantages

Harm: Your rights, interests and well-being will not be harmed. Privacy risks have been minimized.

Risks: An allergic skin reaction (redness) due to wearing the brace is a potential harm. You should stop

wearing the brace and contact TOPMED if this occurs.

Bruises, corns, scratches and/or pain may appear on the fitted limb, due to poor orthotic fit or incorrect placement. An orthotist will be present all appointments to ensure the best possible fit of the orthosis. You can contact the balance clinic during the fitting period to schedule an adjustment meeting. During trial periods, you can contact TOPMED for advice and services as needed. Another possibility is injury due to appliance breakage.

Benefits: There will be no immediate benefit from your participation, except the benefit of trying a new orthosis that may improve your quality of life. The benefit of your participation is that it will provide empirical data on orthosis wear. This is an advantage for Laboratoires Victhom Inc.

Informational risks are limited by the conditions mentioned in the "Privacy and confidentiality" section, and by the professional commitment of the project team.

Information requested

We will collect data on your age, weight, height and several other anthropometric measurements of your fitted thigh. Photos of your leg wearing the brace will also be taken on several occasions.

You will be asked several questions about your physical and psychological symptoms, your comfort, your appreciation of the orthosis and its ease of fitting.

You will be asked to complete a wear diary during the trial periods, detailing the duration of total daily wear, as well as the duration of sitting, physical and sporting activities performed during the day, the number of removals and adjustments of the brace, any discomfort experienced and medication taken.

Privacy

As this is a research and development project for an innovative product, you are required to maintain confidentiality so as not to interfere with the company's eventual marketing of the product.

Project sponsor

Natural Sciences and Engineering Research Council of Canada (NSERC)

Laboratoires Victhom Inc.

Project team remuneration

Members of the project team are remunerated by an NSERC grant and by Victhom Laboratories Inc.

Marketing

It is possible that a commercial product may be developed by Laboratoires Victhom Inc. as a result of this research (see contact details below). If this is the case, you will receive no direct or indirect benefit.

Laboratoires Victhom Inc.

100-2101 boulevard Le Carrefour

Laval (Québec), H7S 2J7, Canada

Choosing to participate in the project

You have the choice not to participate in this study and/or to participate in future research projects with TOPMED. You also have the option of discontinuing your participation in this study at any time without penalty. The services you receive from Clinique Équilibre will not be affected in any way. You may notify any member of the project team of your intention to stop participating verbally or in writing:
Marianne Lancelot/Catherine Lavoie/Élizabeth Lafrance, Orthotist-Prosthetist, TOPMED
Tel.: (418) 780-1301
E-mail: etudes@topmed.ca

Privacy and confidentiality

Information gathered from questionnaires, photos, logs and anthropometric measurements is confidential and will be used only for the purposes of this research project, unless otherwise agreed by the participant. All data collected, notes, photos and computer recordings are encrypted on servers.

All questionnaires and digital logs have been created using the Lime Survey platform. The information processed is hosted in Canada on the platform's encrypted servers (Secure Socket Layer procedure), which comply with the RGPD standard

Unless required by law, we will not disclose or publish any information that may directly or indirectly reveal your identity without your prior explicit consent.

Data will be stored in coded form for a period of five (5) years, then anonymized in a database for retention for a period of ten (10) years for statistical reference purposes.

Participants will not be identified by name in trial documentation. They will be assigned a number, relative to the order of their recruitment, which will be used to reference the data collected.

Data access

All research data will be accessible to the project team. Project sponsors will not have access to research data. Participants will not have access to research data. The Research Ethics Committee, Veritas IRB, will have access to research data for verification in the event of a complaint. Where appropriate, data will be made available to them for viewing only via videoconferencing.

Personal injury compensation, legal rights

By signing the consent form, you do not waive any of your legal rights.

Compensation

If required, a parking permit will be provided at the time of your visit. You will receive $50 compensation for your participation in each validation protocol meeting. The total amount awarded will not exceed $350, i.e. the equivalent of the complete protocol with 2 adjustment meetings (optional meetings at your request). The first payment will be made after the first trial meeting. The remainder

of the amount will be distributed at the last meeting or when the participant chooses to end his or her participation.

Voluntary participation and withdrawal

Your participation should be entirely voluntary. You may refuse to take part in this project now, or you may decide to withdraw at any time, without penalty. You may notify any member of the project team of your intention verbally or in writing. In the event of your withdrawal, the data collected will be used under the same conditions indicated in this document, unless you request otherwise.

New information

In the event of any inconvenience arising from the prototype validation test, you will be promptly notified.

For more information?

Contact :
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E-mail : mlancelot@topmed.ca

Ethics review

This study has been reviewed by the Veritas Independent Review Board (IRB). If you have any questions about your rights as a research participant or about the researcher's responsibilities, you can contact the director of Veritas IRB 24 hours a day, 7 days a week at 514-337-0442 or toll-free at 1-866-384 -4221. An IRB is a group of scientific and non-scientific individuals who perform the initial and ongoing ethical review of research projects with the rights and welfare of the subject in mind. If you have any comments, complaints or concerns related to the study, you should first contact the study investigator. Please call the IRB if you need to speak to someone independent of the principal investigator and research staff, and/or if the investigator and research staff could not be reached.

Declaration of consent

I, (print name) _____, acknowledge that I have read the form and understand the information provided to me in order to give informed consent. All my questions have been answered to my complete satisfaction. I have had sufficient time to consider my decision whether or not to participate in this study. I understand that my participation in this study is entirely voluntary and that I may decide to withdraw at any time, without penalty.

I voluntarily consent to participate in this study.

Signature: _____Date : _____

Member of the research team who interacted with the subject

To the best of my knowledge, the information on this consent form and the information I have provided in response to any questions fairly describes the project. I agree to conduct this study in accordance with all ethical standards applicable to projects involving the participation of human subjects. I undertake to ensure that the subject receives a copy of this consent form.

Name (print name) : _____

Signature: _____Date : _____

Principal investigator

I undertake to conduct this study in accordance with all ethical standards applicable to projects involving the participation of human subjects.

Name (print name) : _____

Signature: _____Date : _____