3 May 2018

INFORMED CONSENT

3D-PRINTING AND ACCES TO TELE REHABILITATION (IMP&ACTE3D)

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INFORMED CONSENT

Dear Madam, Sir,

Introduction

Thank you for agreeing to participate in a scientific study.

This study has been approved by an independent ethical committee (UZA Ethics Committee). This study is being conducted in accordance with the guidelines for Good Clinical Practice (ICH/GCP: International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use/Good Clinical Practice) and the most recent version of the Declaration of Helsinki drawn up for the protection of people taking part in clinical trials. Under no circumstances should you consider the approval by the UZA Ethics Committee as an encouragement to participate in this study.

This text has been written to familiarise you with the course of the study. It is important that you understand the information below. However, if this information leaflet contains words that you do not understand, we will of course be pleased to explain them to you.

Aim of the study

The main objective of the study is to carry out a comparison between traditional and 3D printed custom-made orthoses within the Imp&Acte3D research project.

Procedure

The standard treatment is a traditional custom-made orthosis. During the study, this standard treatment will be alternated with a 3D printed custom-made orthosis.

The study will take place at the orthopaedic centre with which you are in contact. As part of this study, you will be monitored for 6 weeks and will have to visit the orthopaedic centre several times during this period. You will undergo 2 treatments during which you will be fitted with an orthopaedic device. You will be given this orthopaedic device to take home with you, where you can wear the orthosis during your daily activities.

After 3 weeks you will be expected at the orthopaedic centre. Here you will have to perform some functional tests, which means walking a few dozen metres with and without your orthosis. You will then be asked to complete a questionnaire about your experiences with the orthosis.

On the same day, you will be given your second orthosis to take home with you, which you can also use for 3 weeks in your daily activities. After this further 3-week period, you will return to the centre for a final analysis. You will again walk a few dozen metres with the orthosis and fill in a questionnaire.

You may take both new orthoses home as soon as the examination is completed. You will be reimbursed for any subsequent travel to this centre.

Risks and inconveniences

Walking with an orthosis may involve some discomfort, such as redness or irritation. In exceptional cases or under heavy load, the orthosis may break, causing your body to suddenly lose support, which may lead to a fall. However, this risk is estimated to be low and of a similar order to the orthosis you are already wearing or have worn.

If you experience symptoms that make it impossible to wear the orthosis, please return to the orthopaedic centre and inform your attending physician.

Participation

As you are participating in this trial voluntarily, you may withdraw from the study at any time without explanation. Whether or not you participate in this study has no influence on whether or not you will receive therapeutic treatment at a later date.

Participation in the study will not entail any (additional) costs for you or your health insurance company. All study-related costs will be borne entirely by the research project.

Confidentiality

Like all medical data, the data collected in the context of the study are treated with the utmost confidentiality. Medical confidentiality, international guidelines (ICH-GCP) and Belgian legislation are respected (including the legal requirements as stipulated in the Belgian Law of 8 December 1992 on the protection of privacy and the Belgian Law of 22 August 2002 on patient rights).

You have the right to view the data collected about you in this study. The study data will be stored and processed in coded form. This means that the data will be coded before they are made available to third parties, i.e. the sponsor and/or his representative(s) can only obtain the data after coding. The code (link between the participant and his/her data) is kept by the researcher/research team. The researcher is therefore the only person who can establish a link between code and participant. The data collected will not contain any elements that could be combined to identify the participant (e.g. combination of initials, gender and full date of birth).

If the results of this study are announced at conferences and published in scientific journals, this will be done without revealing your identity.

Rights of the study participant

Any person asked to participate in this study has the right to:

1. To be informed about the nature of the study

2. Be informed of the procedures of the study, the equipment and material that will be used in the study

3. Be given a description of the possible risks and inconveniences that may occur as a result of the study

4. An explanation of the potential benefits that can be expected as a result of the study

5. An explanation of any alternative procedure, device or treatment that may be of benefit to the patient, and its advantages and disadvantages.

6. Be informed of the medical treatment options available to the patient after the study if complications should arise

7. To be given the opportunity to ask questions about the study or the procedure being followed

8. Be informed that the agreement to participate in the medical study may be revoked at any time and that the patient may interrupt his participation without further justification.

9. To obtain a copy of a signed and dated agreement if requested.

10. To give his/her agreement or non-agreement to participate in the study without experiencing any kind of pressure from the researchers

CONSENT FORM

Imp&Acte3D

1. I confirm that I have read and understood the information about this study and that I have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I can withdraw from the study at any time without giving a reason.

3. I understand that the data recorded are important to the study. I know that only the researchers will view and analyse it. I authorise the use of this data to achieve the aims of the study.

4. I understand that participation in this study has no implication for receiving therapeutic treatment.

5. I have had sufficient time to decide about participation in this study.

6. I agree to participate in this study.

Name participant Date Signature

Name Researcher Date Signature