

GENERAL STUDY INFORMATION AND INFORMED CONSENT

UNIVERSITY CEU CARDENAL HERRERA

Principal investigator: Dr. Sergio Montero Navarro

**TITLE: EFFECTIVENESS OF A PROTOCOLIZED TREATMENT OF SPECIFIC
PHYSIOTHERAPY FOR SUBJECTS SURGICALLY OPERATED BY
ARTHROSCOPY FOR FEMOROACETABULAR SYNDROME**

Research and Ethics Committee of General University Hospital of Elche Number PI
6/2019

NCT ID:

DATE: 20-05-2019

GENERAL STUDY INFORMATION

TITLE: EFFECTIVENESS OF A PROTOCOLIZED TREATMENT OF SPECIFIC PHYSIOTHERAPY FOR SUBJECTS SURGICALLY OPERATED BY ARTHROSCOPY FOR FEMOROACETABULAR SYNDROME

PRINCIPAL INVESTIGATOR: Sergio Montero Navarro, physiotherapist (PhD)

1) Information to the participant of the object of the study:

The goal of this study is to determine the effectiveness of the Müller & Puig protocol for postoperative physiotherapeutic treatment for subjects undergoing hip arthroscopy due to femoro-acetabular shock. From a protocol of generic physiotherapy for the rehabilitation of the hip, a new one is created, adapted to the characteristics of the femoro-acetabular syndrome and the consequences of its intervention through arthroscopy.

If you agree to participate in this study, you will be asked to complete a survey and undergo anthropometric measurements in approximately 30 minutes of your time.

Participation in this study is strictly voluntary. If you have any questions about this project, you can ask questions at any time during your participation. Likewise, you can withdraw from the project at any time without it harming you in any way. Any important finding that could be a risk to your health will be communicated and addressed immediately.

Expected benefits: The protocol proposed in this study should have an impact on a faster and wider recovery of hip joint functionality after surgery compared to the general protocol of hip rehabilitation.

Anticipated risks: No additional risk is anticipated to those of conventional treatment.

2) Protection of personal data:

In accordance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council, of April 27, 2016, concerning the protection of natural persons with regard to the processing of personal data and the free movement of personal data, I have been informed that my personal data, obtained by completing this form as well as those resulting from my participation in the project will be treated under the responsibility of ALICANTE CLINIC, with the purpose of managing my participation in this research project.

This study was approved by the Research and Ethics Committee of General University Hospital of Elche (PI 6/2019).

INFORMED CONSENT

EFFECTIVENESS OF A PROTOCOLIZED TREATMENT OF SPECIFIC PHYSIOTHERAPY FOR SUBJECTS SURGICALLY OPERATED BY ARTHROSCOPY FOR FEMOROACETABULAR SYNDROME

Principal Investigator: Dr. Sergio Montero Navarro

Name _____

ID Number _____

Free and voluntary

MANIFEST:

1. I have read and understood the fact sheet of the study.
2. I have had the opportunity to ask questions.
3. My questions have been answered satisfactorily.
4. I have received sufficient information from the study and the tests to be performed.
5. I understand that participation is voluntary and I can leave the study whenever I want without having to give explanations and without affecting my medical care.
6. In accordance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and the free circulation of these data and repealing Directive 95/46 / EC, I have been informed that my personal data, obtained through the completion of this form as well as those resulting from my participation in the project will be treated under the responsibility of the CLINIC ALICANTE, with the purpose of managing my participation in this research project. In addition, I have been informed of the following aspects:
 - a. That the preparation of profiles is planned in order to analyze or predict aspects related to my health.
 - b. That the indicated treatments are legitimized in the consent granted by me.
 - c. That my personal data, obtained through the completion of this form, as well as those resulting from my participation in the project will be retained

for the time necessary for the development of this research, estimated to be 18 months, being subsequently destroyed, without being able to be preserved without having been previously anonymized. In any case, they can not be assigned without my express consent and I do not grant it in this act.

- d. That I can contact the Delegate of Data Protection of CLINICA ALICANTE, directing my request in writing to the postal address C / Jaime Segarra nº 2 - 03010 Alicante or to the e-mail address clinicaalicante@clinicaalicante.com
7. That in accordance with the rights conferred on me by the current regulations on data protection, I may contact the competent Control Authority to present the claim that I consider appropriate, as well as be able to exercise the rights of access, rectification, limitation of treatment, deletion, portability and opposition to the treatment of my personal data and withdraw the consent given for the treatment thereof, directing my request to the responsible researcher at the contact address contained in this document.
8. I agree that my written consent and other data are available to the clinical research project in which I am participating, and to the researcher responsible for it, José Martín Botella Rico, but always respecting confidentiality and ensuring that my Data will not be publicly available so that it can be identified.
9. I sign this information and consent form voluntarily to express my desire to participate in this research study on the effectiveness of a protocolized treatment of specific physiotherapy for subjects undergoing arthroscopy for femoroacetabular syndrome, until it decides otherwise. By signing this consent, I do not waive any of my rights. I will receive a copy of this document to save it and be able to consult it in the future.

Therefore, I give my consent and consent to carry out the detailed study with the help of the personnel that is necessary with the appropriate qualification and specialization.

The participant

(Signature) Name, Surname

Elche, Date

INVESTIGATOR

Mr. Sergio Montero Navarro

Email: jmbotella@uchceu.es

Phone: 965426486. Ext. 67516

Researcher of the CEU-Cardenal Herrera University of Valencia, I declare that I have provided the study participant and / or authorized person with all the information necessary to carry out the intervention specified in this document and I declare to have confirmed the absence of contraindications, as well as have taken all the necessary precautions so that the intervention is correct.

Elche, Date _____

REVOCACTION OF INFORMED CONSENT

ID Number

I revoke the consent given on the date of

And I do not want to continue the treatment I give on this date.

Date: _____