GENERAL STUDY INFORMATION AND INFORMED CONSENT

UNIVERSITY CEU CARDENAL HERRERA

Principal investigator: Dr. Sergio Montero Navarro

TITLE: Ultrasound Probe Pressure on the Intratendon Doppler Signal in Patellar Tendinopathy

Research and Ethics Committee of CEU Cardenal Herrera University Number: CEI20/073

NCT ID:

DATE: 12-09-2020

CONSENT DOCUMENT FOR PARTICIPATION IN A RESEARCH PROJECT

EVALUATION OF THE INFLUENCE OF ULTRASOUND PROBE PRESSURE ON THE INTRATENDRON DOPPLER SIGNAL ON PATELLAR TENDINOPATHY

Principal investigator: Dr. Sergio Montero Navarro

NAME:_____
ID No._____
Freely and voluntarily

Manifest:

1. I have read and understood the fact sheet under 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 at any time without explanation and without affecting my medical care.
6. In accordance with 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 on the free movement of such data and repealing Directive 95/46/EC, 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 processed under the responsibility of the UNIVERSITY FUNDATION SAN PABLO CEU (hereinafter, FUSP-CEU), in order to manage my participation in this research project. In addition, I have been informed of the following aspects:
    a. Profiling is planned to analyse or predict aspects of my health.
    b. That the treatments indicated are legitimized in the consent granted by me.
    c. That my personal data, obtained by completing this form, as well as those resulting from my participation in the project will be kept for the time necessary for the development of this research, which is estimated to be1 1 months, being subsequently destroyed, without being preserved without having previously been anonymized. In any case, they may not be transferred without my express consent and I do not grant it in this act.
    d. That I can contact the Data Protection Officer of FUSP-CEU, directing my written request to the postal address C/ Tutor no. 35 - 28008 Madrid or to the email address dpd@ceu.es.
    e. That in accordance with the rights conferred on me by the current legislation on data protection I may contact the competent Supervisory Authority to submit the complaint that it deems appropriate, as well as I may exercise the rights of access, rectification, limitation of processing, deletion, portability and opposition to the processing of my personal data and withdraw the consent given for the processing thereof, directing my request to the responsible investigator at the contact address contained in this document.
7. I agree that my written consent and other data are available to the clinical research project in which I am participating, and the researcher responsible for it, Sergio Montero Navarro, but always respecting the confidentiality and assurance that my data will not be publicly available in a way that can be identified.
8. The data collected for this study will be included, with those of other persons participating in this study, in a personal database of the CEU Cardenal Herrera University, to which only the researchers approved for this project will have access, all of

them being subject to the secret inherent in their profession or derived from a confidentiality agreement.

9. I voluntarily sign this information and consent document to express my desire to participate in this research study on the assessment of the influence of ultrasound probe pressure on the intratendon Doppler signal on patellar tendinopathy, until I decide, otherwise. By signing this consent, I do not renounce any of my rights. I will receive a copy of this document to save it for future reference.

I therefore consent and consent to the detailed study with the help of the necessary staff with due qualification and specialization.

The participant
(Signature) Name, Last Name

Elche, a .... 20....

FAMILY OR TUTOR AUTHORIZATION

In the face of the impossibility of _____
with ID_____ to provide authorization for the treatments expressed in this document freely, voluntarily, and consciously.
NAME:_____
with ID_____
As a (husband, wife, child, brother, legal guardian, family member, close friends, caregiver), I decide, within the available clinical options, to give my free, voluntary and conscious consent to the technique described for the treatments set out herein.

ELCHE, of _____of_____

Researcher

Dr. SERGIO MONTERO NAVARRO
ID: 74372902X
Email: sergio.montero@uchceu.es
Phone: (34) 96 542 64 86 ext. 67704

Researcher at 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 for the realization of the intervention explained in this document and declare that I have confirmed, immediately prior to the application of the technique, that the participant does not incur any of the contraindication cases related above, as well as having taken all the necessary precautions for the correct intervention.

Elche,_____of _____of_____

REVOCATION OF INFORMED CONSENT

NAME:_____
with ID:_____
I revoke the consent given on the date of_____
And I do not wish to continue the treatment I give on this date.

_____, _____de _____de_____

PARTICIPANT INFORMATION

STUDY TITLE:
EVALUATION OF THE INFLUENCE OF ULTRASOUND PROBE PRESSURE ON THE INTRATENDRON DOPPLER SIGNAL ON PATELLAR TENDINOPATHY.

PRINCIPAL INVESTIGATOR: Dr. Sergio Montero Navarro.

1) Information to the participant of the study object:

An ultrasound scan will be performed in Doppler mode on the patellar tendon. The scan will be performed with different pressures on the, simulating the pressure that a clinician can perform during ultrasound examination. To generate the different pressures,, an articulated arm with a force meter to which the probe is attached will be used. Ultrasound videos (Doppler) of each pressure exerted will be recorded. After that, they will be stored for further image analysis. This procedure is safe, painless and may take about 15 minutes.

The objective of this study is to evaluate the influence of ultrasound tube pressure that the clinician may exert during the patellar tendon scan on the signal image of the vessels inside the affected tendon.

This study was approved by the Research and Ethics Committee of CEU Cardenal Herrera University (CEI20/073)

2) Protection of personal data:

In accordance with 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 on the free movement of such data and repealing Directive 95/46/EC, 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 processed under the responsibility of the UNIVERSITY FUNDATION SAN PABLO CEU (hereinafter, FUSP-CEU), in order to manage my participation in this research project.

Name and surname of the researcher:

Dr. Sergio Montero Navarro
ID: 74372902X:
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E-mail: sergio.montero@uchceu.es
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STUDY PROTOCOL PLAN AND STADISTICAL ANALYSIS PLAN (SAP)

UNIVERSITY CEU CARDENAL HERRERA

Principal investigator: Dr. Sergio Montero Navarro

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STUDY PROTOCOL PLAN

Objectives:

The objectives of our study have been the following:

- Analyze the influence of the pressure exerted on the probe on the variables of area, number of signals, pixel intensity, perimeter, solidity, perfusion index, circularity, major and minor diameter of the intratendon Doppler signal in the evaluation of patellar tendinopathy.

- To study the relationship between the pressure exerted on the probe and intratendon perfusion in the Doppler evaluation of patellar tendinopathy.

Volunteers who want to participate in the study will read the general information of the study and sign the informed consent to participate in the study.

Once the informed consent has been read and delivered, the evaluator will check that they meet the inclusion criteria.

A quasi-experimental study of a single group will be carried out, consisting of subjects with patellar tendinopathy with intratendon hyper vascularization. Intratendon vascularization will be quantified using a proprietary methodology using ImageJ 1.47v image analysis software, determining the different variables related to the Doppler signal within an intratendon region of interest.
The first contact with the patient likely to participate in the project will always be made by the same researcher who will duly inform them of the study and provide informed consent in case of accepting participation for the performance of the exploratory ultrasound. Subsequently, a general questionnaire will be completed, where sociodemographic data and other data referring to the injury and sports practice are collected, also adding the VISA-P questionnaire that assesses the symptomatic severity, the severity of the symptoms and the capacity functional function in patients with patellar tendinopathy. Lastly, the ultrasound examination will be carried out in power-Doppler mode.

The ultrasound examination will begin with the positioning of the patient on the table in

the supine position and with both knees extended. At the level of the knee to be explored, a support with an articulated arm will be placed where the probe attached to the force meter will be fixed. After positioning the articulated arm, a power-Doppler ultrasound scan of the intratratendon vascularization will be carried out, making longitudinal cuts of the patellar tendon and using previously pre-established Doppler optimization parameters for all patients. The optimization parameters of the power-Doppler signal will be set at a Doppler frequency of 6.7 MHz, pulse repetition frequency (PRF) of 0.7 kHz. The lowest wall filter and a standardized gain just below the level that produces random noise will be applied.

This examination will be repeated several times with different probe pressures, which will be quantitatively adjusted through the force sensor and maintained with the articulated arm. A 4-second static video will be recorded of the longitudinal section that presents a higher Doppler signal in each of the scans at different probe pressures.

These videos will be saved for later analysis with ImageJ 1.47v software (Wayne Rasband, National Institutes of Health, USA, 2012) to determine and quantify the presence of intratendon Doppler signal.

The processing and analysis of the videos and images will be carried out on the image with the highest and lowest Doppler signal of each stored video. Once the image has been scaled, a region of interest (ROI) with dimensions capable of encompassing the intratendon Doppler signal will be selected individually.

To quantify the Doppler signal, the saved image with the highest Doppler signal of each video was selected and the area of color pixels was calculated.

To quantify the flux, the pixel color mean of the Doppler signals of each image was calculated. The mean pixel color of the image with the highest signal was considered as data of the maximum systolic velocity, and the one with the lowest signal as the final diastolic velocity. These data were transferred to the IR formula, obtaining a value associated with the intratendinous flow pattern (perfusion index).

In the images that did not detect a Doppler signal, or did not present an intratendon Doppler signal in diastole, the IR was determined as 1, which represents normality in the musculoskeletal tissue.

In addition, the parameters of number of signals, mean intensity of the pixel, area,

perimeter, major and minor diameter, circularity and solidity were automatically calculated on the selected images with the highest Doppler signal of each recording.

This methodology will be carried out following the previously established and standardized order, based on standardized protocols for both subject positioning and echo-Doppler exploration. The ultrasound examination and subsequent analysis of the images will be described exactly and precisely so that they can be easily reproducible. All data obtained will be recorded in a computer spreadsheet to make the final statistical analysis easier and to obtain a greater and faster interpretation of the results.

Statistical Analysis Plan (SAP)

First, all the variables of interest will be detected and later they will be coded, labeled and transferred to a database. A data collection notebook (CDN) will be created where the variables, their reference values, measurement system and interpretation will be described and which will be available to all members of the working group. The programs used will be Microsoft © Access and Excel for initial data registration and IBM SPSS Statistics 19.0 for analysis.

Data debugging and control systems

The data related to the clinical information of the subjects and related to the questionnaires will be recorded in a database created for this purpose (Microsoft Access ©) with data entry protection systems. The same researcher will always record the data and a feedback review will be carried out for the detection of errors and lost cases by a third person. Missing and out-of-range screening will be performed.

The data related to the variables obtained by image analysis of ultrasounds will be exported in an automated way with a macro created for this purpose from the data analysis program in ASCII format to avoid incompatibilities between the image analysis program and the imaging programs. statistical analysis.

Exploratory Data Analysis (EDA)

Qualitative variables will be summarized in the form of counts and relative frequencies and, where appropriate, absolute frequencies and their confidence intervals (95% CI). Graphic summaries will be made using bar diagrams.

The quantitative variables will be summarized by means, standard deviations, medians, and interquartile ranges. Confidence intervals will also be provided for each of the measures. Graphical summaries will be made using box plots and bar diagrams with 95% CI.

A univariate analysis of outliers will be carried out and their influence will be verified through the Z scores. Multivariate analysis of atypical cases and their influence will be carried out using the Mahalanobis distance.

Unusual cases will be removed from the analysis only if it is certain that they are wrong.

It will be checked whether the quantitative variables of interest follow a normal distribution (Kolmogorov-Smirnof test). The normality tests will be accompanied by the Q-Q normality graphs with and without trend that will aid interpretation and decision-making. In the event that any of the variables of interest does not conform to a normal distribution, a transformation of this will be carried out until it is achieved as long as its interpretation is not compromised.

Analysis of data

In the case of fulfilling the assumption of normality, parametric tests will be chosen and if not, the non-parametric alternatives will be chosen.

The measurement pattern used will be randomized, all subjects will be assigned to a minimum or a maximum probe pressure as the start of the measurements. The randomization factor (pressure) is included as a fixed effect, which will prevent a possible

interaction between pressure and the quantification of the Doppler signal.

To perform the statistical analysis, in the case that the variables present normality, the Pearson correlation coefficient will be used for quantitative variables. In order to better visualize the joint behaviour of both variables, scatter diagrams will be added and to determine the effect size and interpret the degree of shared variance, the coefficient of determination will be calculated. In the event that any variable does not present normality, the Spearman Rho correlation test will be chosen.