Research project: *Effects of plantar supports on patients with rheumatoid arthritis by measuring quality of life and activity physical*

This document is provided to give you enough information so that can understand the possible risks and benefits derived from your participation in this project.

Primary Objective:

Observe the differences regarding the quality of life and activity physics among the following groups that will be randomly generated between volunteers who participated in the previous research project ARC0001.

1. Control group, which is composed of patients with Rheumatoid Arthritis (AR) with standardized foot orthoses.

2. TAD action group, which is composed of patients with arthritis Rheumatoid (AR) with foot orthoses made with the Direct Adaptation Technique (TAD)

3. CAD-CAM action group consisting of patients with arthritis Rheumatoid (AR) with foot orthoses made with the Computer technique Aided Desing- Computer Aided Manufaturing (CAD-CAM).

Secondary Objectives:

1. Observe the differences with respect to the number of kilometers between the control and acting groups.

2. Observe the differences between the three selected groups randomly defined above.

3. Observe the differences with respect to the number of hours standing between three randomly selected groups defined above.

Methodology used

The study in which you will participate has been designed at the University of Malaga, Faculty of Health Sciences, Nursing Department Podiatry, area of Orthopedics, by PhD student Laura Ramos Petersen, supervised by Dr. Gabriel Gijón Noguerón.

It will be held at the Virgen de las Nieves University Hospital, under the Clinical supervision of Dr. Rafael Caliz Caliz, Head of the Rheumatology Service and the nurse Andrés Reinoso Cobo.

The three types of foot orthoses used in the study, in which you are going to participate, have been selected by the research team, based on the needs to be covered that have been observed in the study “Classification of degree of foot involvement in Rheumatoid Arthritis ”, in which you participate between the months of January and June 2018.

The study in which you will participate will be provided with a foot orthoses orthopedic and will commit to take them for a year, time required to perform the full study.

The material that will be provided in the study is subsidized by the University of Malaga, Faculty of Health Sciences.

- By signing this document, you agree to return to the research team GENEActiv bracelet.
- However, the foot orthoses given to you at the beginning of the study will be it may remain, without the need for any payment, since the University of Malaga takes care of the expenses.

At all times you can count on the help of the research staff and with the possibility of clarifying any questions that may arise, calling phones that will be provided for control and monitoring.

You will always have the option to leave the study by revoking your consent at any time you consider it, you should never feel forced to continue, or offer explanations of the reason. You should know that your voluntary decision to participate or not in the draft research, will NOT condition at any time the medical assistance that It is provided at the Virgen de las Nieves University Hospital.

The BENEFITS that we hope to obtain with this study are to determine which are the best types of orthopedic insoles that cover the needs of patients with Rheumatoid Arthritis (RA), in the improvement of quality of life of patients with rheumatoid arthritis (RA) and thus being able to develop and recommend more efficient orthopodological treatments for patients with rheumatoid arthritis (RA), and transfer the results to practice clinic. Also inform you that we DO NOT appreciate potential RISKS for volunteers who participate in such research, since it is not necessary to carry out no invasive technique or procedure that endangers integrity of the patient.

We also inform you of the confidentiality and protection of character data personal, according to the Law described below:

From 25th of May 2018, the new data legislation in the EU is fully applicable personnel, specifically Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 Data Protection (GDPR). Therefore, it is important that you know the following information:

- In addition to the rights you already know (access, modification, opposition and cancellation of data) now you can also limit the processing of data that is incorrect, request a copy or that the data that you have provided for the study be transferred to a third party (portability). For exercise your rights, contact the principal investigators of the study Dr. Rafael Cáliz Cáliz (rcalizcaliz@gmail.com) and / or Gabriel A. Gijón Noguerón (gagijon@uma.es). We remind you that data cannot be deleted even if you stop participating in the trial to ensure validity of the investigation and comply with the legal duties and authorization requirements of medicines. You also have the right to contact the Data Protection Agency if you do not You will be satisfied.
- Both the Center and the Promoter are responsible respectively for the treatment of their data and undertake to comply with current data protection regulations. The data collected for the study will be identified by a code, so that it is not included information that can identify you, and only your study doctor / collaborators can relate such data with you and your medical history. Therefore, your identity will not be disclosed to No other person except the health authorities, when required or in cases of medical urgency The Research Ethics Committees, the representatives of the Authority Sanitary inspection and personnel authorized by the Promoter, may only access to check personal data, clinical study procedures and compliance with the standards of good clinical practice (always maintaining confidentiality of the information).
- The Investigator and the Promoter are obliged to keep the data collected for the study at less up to 25 years after completion. Subsequently, your personal information is only keep by the center for your health care and by the promoter for other purposes of scientific research if you had given your consent for it, and if allowed the applicable law and ethical requirements.
- If we transfer your coded data outside the EU to the entities of our group, service providers or scientific researchers who collaborate with us, the Participant data will be protected with safeguards such as contracts or other mechanisms by data protection authorities. If the participant wants to know more at In this regard, you can contact the principal investigator of the project Dr. Rafael Cáliz Cáliz (rcalizcaliz@gmail.com) and / or. Gabriel A. Gijón Noguerón (gagijon@uma.es) If you need any clarification that is not included in this document or

Any questions you may have may be directed to the reference staff.
Sincerely
Gijón Noguerón, Gabriel A

WRITTEN INFORMED CONSENT OF THE PATIENT

Study title: Effects of plantar supports in patients with arthritis rheumatoid by measuring quality of life and physical activity

Name:	
Your signature	**Date** ___/___/_____ DNI:

I have been informed by a member of the research team that have been collected in this document.

I have read the information sheet given to me.

I have been able to ask questions about the study.

I have received enough information about the study.

I understand that my participation is voluntary.

I understand that I can withdraw from the study:

- Anytime.
- Without having to explain.
- Without this having an impact on my medical care.

I freely lend my agreement to participate in the study.

I also give my authorization for the members of the research team authorized by the Virgen de las Nieves University Hospital can use the data collected in your medical history concerning the study disease, Arthritis Rheumatoid, always anonymously as required by current and current legislation.

I have been informed that all data obtained in this study will be confidential and will be treated as established by the Organic Law of Protection of Personal Data 15/99 and by EU legislation on data personnel, in particular Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on Data Protection (GDPR).

I have been informed that the information obtained will only be used for the purposes specific to the study.

I as a researcher / member of the research team commit myself and I guarantee that the data obtained in this study will only be used for the purposes specific of it.

Name:	
Your signature	**Date** ___/___/_____ DNI:

REVOCATION INFORMED CONSENT

By signing this document I declare the revocation of consent Informed signed in which I consented to participate in the study “Effects of the supports plantar in patients with rheumatoid arthritis by measuring quality of life and physical activity”

Name:	
Your signature	**Date** ___/___/_____ DNI:

WRITTEN INFORMED CONSENT OF THE PATIENT LEGAL REPRESENTATIVE

Study title: Effects of plantar supports in patients with arthritis rheumatoid by measuring quality of life and physical activity

Name: **Name legal representative:**

Your signature	**Date** ___/___/___
	DNI:

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