October 10th, 2023

Comparison between Platelet Rich Plasma and Corticosteroids for the Treatment of Rotator Cuff Tendinopathy.

Double Blind Randomized Controlled Clinical Trial

Informed consent

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Principal investigator: Dr Luciano Rossi

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Orthopedics and Traumatology Service

Informed consent

INVITATION TO PARTICIPATE

Because you suffer from rotator cuff tendinopathy, treatment for this pathology has been indicated. For this reason, we invite you to participate in this research study that evaluates 2 possible treatment methods for this injury.

We ask that you read this document carefully to understand what the research study is about and what it means to participate. By signing this document, you will be confirming that it has been explained to you and that you have agreed to participate in it. It is essential that you know the details before making the decision to participate or not.

I am going to give you information and ask you to participate in this study. You don't have to decide today whether to do it or not. Before you decide, you can talk to someone you feel comfortable about researching. There may be some words you don't understand. Please can you interrupt me to give me time to explain.

VOLUNTARY PARTICIPATION

Your participation in this research is completely voluntary. You can choose to participate or not. Whether you choose to participate or not, all services you receive at this hospital will continue and nothing will change. You can change your mind later

and stop participating even if you agreed before.

INFORMATION ABOUT PLATELET RICH PLASMA

The usual treatment for patients with rotator cuff tendinopathies like the one you suffer from, and in whom conservative treatment has failed (including anti-inflammatories, analgesics and rehabilitation) is infiltrations of the diseased tendon. Platelet-rich plasma (PRP) is a preparation that is made by centrifuging your own blood and obtaining blood factors called platelet growth factors from that preparation. These substances have been shown to improve the healing of musculoskeletal injuries such as skin ulcers, tendon problems and bone healing problems. Platelet-rich plasma has been used for the treatment of musculoskeletal injuries for more than a decade in the United States, Europe, and Asia. There are numerous research studies in humans demonstrating its clinical effectiveness to improve pain and reduce inflammation in other tendinopathies of the musculoskeletal system such as tendonitis of the elbow, hip, knee and ankle. At the Italian Hospital of Buenos Aires we have a lot of experience in the use of this treatment not only in pathologies of the shoulder tendons like the one you have now, but also in the knee, hip, foot and upper limb.

PURPOSE OF THE STUDY

Studies in animals and humans have shown that infiltrations of platelet-rich plasma (PRP) into the pathological tendon in patients with tendinitis like the one you have now, reduces inflammation and relieves pain.
In this study we will continue with this line of research, evaluating the effects of PRP on inflammations that do not respond to usual conservative treatment like the one you have. The objective of the study is to evaluate whether PRP relieves pain in patients with shoulder tendonitis.

TYPE OF INTERVENTION AND RANDOMIZATION

If you agree to participate in the study, you will be randomly assigned to receive one of the following treatments:

Group 1: Infiltration of your shoulder with a corticosteroid + rehabilitation with kinesiology

Group 2: Infiltration of your shoulder with platelet-rich plasma + rehabilitation with kinesiology

Random designation means that you have an equal chance of participating in group 1 or group 2.

Post-infiltration rehabilitation does not vary. That is, you will carry out the same rehabilitation protocol regardless of the group to which you are assigned, which will be in charge of the shoulder rehabilitation team at the Italian Hospital in Buenos Aires.

POSSIBLE EXPECTED BENEFITS/RISKS

Platelet-rich plasma (PRP) is a product generated from your own blood therefore the risks associated with its use are very low. Depending on the results of our research and if our hypothesis that PRP improves pain and general shoulder function more significantly than corticosteroids is confirmed, it could happen that you will not benefit if the treatment is randomly assigned. It's the corticosteroid group. However, there is also the possibility that we will not find an important difference in clinical improvement between both treatments. Thus, while there may be no direct benefit to you from participating in this study, your participation will likely help us find an answer to the research question..

RIGHT TO REFUSE

You do not have to take part in this research if you do not wish to do so. You can stop participating in the research at any time you want. It is your choice and all your rights will be respected.

ALTERNATIVES TO PARTICIPATION

If you do not wish to take part in the research, you will be provided with the standard treatment available in the hospital. That is, the rehabilitation treatment with the hospital's team of kinesiologists and, if desired, an infiltration

with your man's corticosteroids without this implying the need to participate in this protocol.

CONFIDENTIALITY

All your data will be protected in accordance with Law 25326. You have the right to access your personal data at no cost, every six months at least, unless there is a genuine and reasonable interest. You also have the right to request rectification of your data."

COSTS

All interventions and studies carried out during treatment will be free of charge, and you can stop participating at any time you wish without having to justify why you make that decision.

If you suffer any adverse effect or complication, it will be treated immediately and free of charge in the orthopedics and traumatology service of the Italian Hospital of Buenos Aires.

APPROVAL OF THE CEPI AND AUTHORIZATION OF THE MEDICAL DIRECTORATE

The Ethics Committee for Research Protocols (CEPI) of the Italian Hospital of Buenos Aires approved the protocol of the following study and the medical management of the Italian Hospital of Buenos Aires authorized its execution.

CONTACTS OF THE PRINCIPAL INVESTIGATOR AND THE ETHICS COMMITTEE

Below is the cell phone and email of the main researcher of the project, Dr. Luciano Andrés Rossi, an associate physician in the Orthopedics and Traumatology service of the hospital, to whom you can ask any questions you want and consult if you have any problems. .

Luciano Andrés Rossi: 1558733374 - luciano.rossi@hospitalitaliano.org.ar

If you have any questions about your rights as a research subject, or complaints regarding this study, you should call the Research Protocols Ethics Committee, whose director is Dr Augusto Pérez. These committees were established to help protect the rights of research subjects. The contacts of

Ethics Committee are: CEPI | Juan D. Perón 4190 - 4192 Capital Federal, (C1199ABB) | Tel: (005411) 4959-0200 ext. 8425 e-mail: cepi@hospitalitaliano.org.a

DECLARATION OF CONSENT

The purpose of this study, the procedures that will be followed, and the risks and benefits have been explained to me. I have had the opportunity to ask all the questions I had, and they have been answered satisfactorily. They informed me who I should contact if I have other questions. I have read this informed consent document and confirm my participation in this study. I understand that I can withdraw at any time without affecting my future medical care.

Name and surname of Patient	Business	Document number and type	Date	Hour
Name and surname of Witness	Business	Document number and type	Date	Hour
Name and surname of Doctor	Business	Document number and type	Date	Hour