CALCIFYING TENDINOPATHY OF THE ROTATOR CUFF: BARBOTAGE VS SHOCK WAVES

BOTCH (5775)
29/11/23

PATIENT INFORMATION SHEET

HURS

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Study title	**CALCIFYING TENDINOPATHY OF THE ROTATOR CUFF: BARBOTAGE Vs SHOCK WAVES**
Study code	**BOTCH (1619-N-23)**
Principal Investigator	**Javier Muñoz Paz**
Center	**Reina Sofia University Hospital of Cordoba**
Sponsor	**None**

1º INTRODUCTION

You have been invited to participate in a research study. This consent document contains information that will help you decide if you wish to participate. The decision to participate in this study is entirely yours; if you decide not to participate your care will not be affected in any way. Even if you say yes at this time, you may leave the study at any time. Take your time, read this consent document carefully, and ask the doctor or study staff any questions you wish. Do not sign this document until you understand all of the information presented on the following pages and all of your questions about the study have been answered to your satisfaction. You may discuss it with your family and friends if you wish.

The study has been approved by the **Comité de Ética de la Investigación Biomédica de Andalucía.**

Our intention is that you receive correct and sufficient information so that you can decide whether or not to participate in this study. To this end, please read this information sheet carefully and we will clarify any doubts you may have. In addition, you can consult with the people you consider appropriate

2º VOLUNTARY PARTICIPATION

You are invited to participate in the study because you have been diagnosed with **calcifying rotator cuff tendinitis.**

You should know that your participation in this study is voluntary and that you may decide NOT to participate. If you decide to participate, you may change your decision and withdraw your consent at any time, without altering your relationship with your physician or harming your health care.

3º OBJECTIVE OF THE STUDY

The main objective is to compare the results obtained between barbotomy and shock waves in patients with **calcifying tendinitis of the rotator cuff** according to the evolutionary stage of the lesion.

4º DESCRIPTION OF THE STUDY

This study is proposed to be carried out in **28 patients for each group**. They should be between **30 - 60 years of age** and present omalgia lasting more than **3 months**. Radiographic and ultrasound visualization should show rotator cuff calcifications of a size **≥ 5 millimeters (mm).**

These patients can receive two types of treatments which are shock waves or barbotage.

In relation to **shock waves**, these will be given using a 15 mm transmitter in continuous mode with pressure at 3 bar, frequency 12Hz and 3000 impacts. The number of sessions will be between **4 - 8** according to the patient's clinical condition with a rest between sessions of 5 to 10 days.

The **barbotage** will be performed with **1 session** in which the following actions will be performed:

- First, a **suprascapular nerve block** will be performed with corticosteroid and anesthetic (bupivacaine 3 ml) in an ultrasound-guided manner.
- Next, **the calcification will be infiltrated** with 5 ml of local lidocaine and preloaded physiological saline solution under ultrasound guidance.
- Finally, **repeated suctioning** with physiological saline will be performed to extract the calcium in an echoguided manner.

After these interventions**, the patients will receive check-ups at 1, 3 and 6 months after the intervention** in order to see the evolutionary process after the treatment received.

The decision for each treatment will be made randomly, dividing the **patients in a 1:1 ratio** according to whether they attend the initial consultation and the previous patient has received one or the other treatment. There is no use of placebo in this study.

Initial consultation	1 month	3 month	6 month
Age Gender Type of therapy Diseases Number of calcifications Size Previous treatment Location Joint balances (measurement with goniometer) VAS_{in} Latineen Test	Joint balances (measurement with goniometer) VAS_{1m} Latineen Test	Joint balances (measurement with goniometer) VAS_{3m} Latineen Test	Joint balances (measurement with goniometer) VAS_{6m} Latineen Test PGI – I CGI - GI

5º STUDY ACTIVITIES

Patients will be collected. As indicated in the previous section, **they will receive check-ups at 1, 3 and 6 months** after the intervention in order to see the evolutionary process after the treatment received. In these consultations different variables will be collected in relation to the normal process of the disease and that would be taken routinely in this consultation.

6º RISKS AND INCONVENIENCES ARISING FROM THEIR PARTICIPATION

The techniques used and the drugs described above are included within the indications approved and endorsed for their use in our environment.

In relation to the possible risks that may be encountered, we expose that:

- **In relation to barbotomy:**

  Frequent

  - Peritendinous infiltration may cause mild local reactions such as redness and pain, which disappear in a few days without the need to associate another therapeutic measure. The early and temporary appearance of facial flushing is frequent.

  - Adverse effects typical of corticosteroids may appear (elevation of glycemia, blood pressure, atrophy of the subcutaneous tissue).

  Infrequent

  - Allergic reactions (from minor symptoms to anaphylactic reaction) to any of the injected components, so if you know beforehand that you have any known allergy you should inform your doctor before administration.

  - Injury of the tendons, even rupture, near the puncture site. Infection at the puncture site.

- **In relation to shock waves:**

  Frequent.

  - Patients may experience pain during or as a result of the treatment. Generally, the pain diminishes or disappears at the end of the session and may appear one or two days later, requiring in some cases, the intake of some analgesic. Occasionally, erythema (reddening of the skin) may occur in the area where the shock waves are applied.

  - Only in exceptional cases are subcutaneous hematomas observed, which are controlled with the application of local ice during the first days. No other side effects have been documented in these applications.

  Infrequent.

  - Marked pain and redness or hematoma in the area where the shock waves penetrate.

Risks related to the clinical situation of the patient.

- It is essential to ensure the absence of pregnancy in women of childbearing age.

- The application of this treatment is contraindicated in patients with pacemakers, in patients with skeletal immaturity, application in the pulmonary area, infections or tumors located in the area of application.

7º POTENTIAL BENEFITS

The possible benefits of this type of therapy are focused on **the reduction of pain and recovery of functionality**, as close as possible to the situation prior to the pathology. All this would therefore entail indirect benefits such as the reduction of analgesic intake, sleep improvement ...

Among the possibilities is that you may not obtain any health benefit.

8º CONTACT IN CASE OF QUESTIONS

If you have any questions during your participation, you can contact **Dr. Muñoz Paz** through the Rehabilitation Service at **957010948** during office hours 9:00 am - 3:00 pm or go to the service itself.

9º ALTERNATIVE TREATMENTS

Among the available alternatives are treatment with oral drugs and surgery.

10º EXPENSES AND FINANCIAL COMPENSATION

You will not have to pay for medications or study-specific tests. Your participation in the study will not involve any additional costs to your usual clinical practice.

11º PROTECTION OF PERSONAL DATA

The project will be subject to the rules of good clinical practice and will comply at all times with the ethical precepts contained in the declaration of Helsinki, always ensuring compliance with the organic law 3/2018 on the protection of personal data.

- What your data will be used for:

  - To understand how the study treatments work.

  - To better understand the disease being studied and associated health problems.

  - To learn from previous studies to plan new studies or improve scientific analysis methods.

  - To publish research results in scientific journals or use them for educational purposes.

12º COLLECTION OF BIOLOGICAL SAMPLES

Not necessary in this study.

13º OTHER ASPECTS

Any new information concerning the drugs used in the study that may affect your willingness to participate in the study, which is discovered during your participation, will be communicated to you by the investigators as soon as possible.

You should be aware that you may be excluded from the study if the study sponsor or investigators deem it appropriate, either for safety reasons (your condition not responding adequately, any adverse events

occurring from the study medication, etc.) or because they feel that you are not complying with established procedures. In either case, you will receive an adequate explanation of the reason for your withdrawal from the study.

By signing the attached consent form, you agree to comply with the study procedures outlined to you.

__Yes __NO authorize

Sometimes during the intervention, unforeseen findings occur, which may lead to changes in the intervention,

variations that were not initially contemplated may be used.

__YES __NO authorize

Occasionally, images, photos and videos may be taken. They will serve to better document the case and for teaching purposes.

teaching purposes, but will always be confidential.

__SI __NO authorize

you or any authorized person would like more information, please do not hesitate to consult with your responsible physician or any of the medical

or any of the medical staff of the Service that attends you.

13º ACKNOWLEDGEMENTS

Whatever your decision, the research team would like to thank you for your time and attention.

INFORMED CONSENT

Mr./Mrs./.....Age.....

D.N.I:..... NHC.....

Address.....

N° telephone...../Mobile.....

Sticker

MANIFEST

That I have been informed by Dr..... ..... on

...../...../..... (and that I have been given a copy of the information) of the procedure: ..... and also of the expected benefits and the type of risks involved in its performance (most frequent complications) and its non-performance, as well as of the possible alternatives according to the healthcare resources of this Center.

I understand all the information provided to me and my doubts have been satisfactorily clarified.

I CONSENT:

To the physicians of the Med. Physical Medicine and Rehabilitation Service to perform the referred procedure and the necessary complementary tests. I am aware that in case of emergency or unforeseen causes, the necessary medical actions may be performed to keep me alive or prevent me from harm.

I know that I may revoke my consent at any time.

Due to incapacity or waiver of decision making: Authorizing person (family member or legal guardian)

Mr./Ms. ....., with ID: ....

in the capa..... .....

I sign two copies in CÓRDOBA, at ..... of ..... of .....

Signature of the patient **Signature of the legal representative** **Signature of the physician**

I have decided to REVOKE my consent to the above procedure.

Signature of the patient **Signature of the legal representative** **Signature of the physician**

(sign only in case of revocation of previous consent). Date: ...../...../.....