COMPARISON OF HYDRODILATION RESULTS AT DIFFERENT VOLUMES IN ADHESIVE CAPSULITIS BY PHASES

HYCAFVOL (6103)
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PATIENT INFORMATION SHEET AND INFORMED CONSENT

HURS

PATIENT INFORMATION SHEET – Version 1 (19/11/24)

Study Title	COMPARISON OF HYDRODILATION RESULTS AT DIFFERENT VOLUMES IN ADHESIVE CAPSULITIS BY PHASES
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1º INTRODUCTION

You have been invited to participate in a research study. This consent form contains information that will help you decide whether you want 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 now, you can leave the study at any time. Take your time, read this consent form carefully, and ask the doctor or study staff any questions you may have. Do not sign this form until you understand all the information presented in the following pages and all 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 **Biomedical Research Ethics Committee of Córdoba.**

Our intention is for you to receive accurate and sufficient information so that you can decide whether or not to participate in this study. To do so, please read this information sheet carefully, and we will answer any questions you may have. You may also consult with anyone you deem appropriate.

2º VOLUNTARY PARTICIPATION

We invite you to participate in the study because you have been diagnosed with adhesive capsulitis.

You should be aware 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 mind and withdraw consent at any time, without affecting your relationship with your physician or harming your healthcare in any way.

3º OBJECTIVE OF THE STUDY

The main objective focuses on comparing the results obtained between the different volumes of physiological saline solution with which this technique can be performed in patients with adhesive capsulitis according to the stage of the lesion.

4º STUDY DESCRIPTION

This study is planned for 16 patients per group. Patients must be between 30 and 70 years of age and present with shoulder pain lasting more than 3 months, accompanied by limited shoulder joint balance during both active and passive movements. The inclusion and exclusion criteria are outlined below:

Inclusion Criteria:

- Patients aged 30-70 years.
- Shoulder pain lasting more than 3 months.
- Limited ROM, both active and passive.

Exclusion Criteria:

- Lidocaine + test with improved ROM. (4)
- Conditions that preclude treatment (active cancer, tissue infection, oral anticoagulant therapy, cardiac arrhythmias, etc.)
- Previously receiving HD treatment in less than 1 year.
- Stage 0 or 3 AC.
- Non-adherence to the FST program, with attendance rates exceeding 20%.
- Presence of conditions that can cause similar symptoms, such as acromioclavicular osteoarthritis, labral injury, massive rotator cuff tear, or rheumatic diseases.
- Intra-articular corticosteroid injections for less than 2 months.

Patients will be diagnosed and classified based on the stage of their adhesive capsulitis. Subsequently, all patients will receive the same type of treatment based on a hydrodilation technique at different volumes, followed by physical therapy.

The process of assigning patients to different volumes will be predetermined and randomized. This assignment will be carried out using an algorithm created in an Excel database. Only Javier Muñoz Paz will be aware of this assignment, and he will safeguard the information until the end of the study to prevent interference with the results obtained and thus avoid potential bias.

Procedures

First, a nerve block will be performed under ultrasound guidance using 4 ml of anesthetic + 0.5 ml of corticosteroid. Fifteen minutes after the procedure, the ultrasound-guided procedure will begin. The presence of the joint cavity will be confirmed by introducing physiological saline solution and observing its reflux. Subsequently, 5 ml of anesthetic + 0.5 ml of corticosteroid will be introduced, subsequently topping up the predetermined volume with saline solution. Finally, gentle release manipulations will be performed passively without forcing pain.

5º STUDY ACTIVITIES

Patients will be recruited until the required sample size is complete. As indicated in the previous section, they will receive follow-ups at 1, 3, and 6 months after the intervention to assess their progress following treatment. During these visits, various variables related to the normal course of the disease will be collected. These variables will be routinely collected: age, gender, previous treatments, medical conditions, time since onset of symptoms, joint recess size with ultrasound, joint balance; and function and pain scales: SPADI, VAS, LATTINEN.

6º RISKS AND DISCOMFORT ARISING FROM YOUR PARTICIPATION

The techniques used and medications described above are included within the approved and approved indications for use in our setting. This type of technique is a common treatment for your condition.

Regarding the potential risks that may be encountered, we state the following:

Frequent

- Infiltration may cause mild local reactions such as redness and pain, which disappear within a few days without the need for additional therapeutic measures. Early, transient facial flushing is common.
- Adverse effects associated with corticosteroids may occur (elevated blood glucose, elevated blood pressure, and subcutaneous tissue atrophy).

Uncommon

- Allergic reactions (ranging from minor symptoms to anaphylactic reaction) to any of the injected components. Therefore, if you know of any known allergies, you should inform your doctor before administration.
- Tendon injury, including rupture, near the injection site. Infection at the injection site.
- Temporary depigmentation of the injected area.

Risks related to the patient's clinical condition.

- It is essential to ensure that there is no pregnancy in women of childbearing age.
- This treatment is contraindicated in patients with pacemakers, infections, or tumors located in the injection site.

7º POSSIBLE BENEFITS

The potential benefits of this type of therapy focus on pain reduction and restoring the function of the affected shoulder to as close to what it was before the condition, shortening the natural progression of the disease. All of this, therefore, would entail indirect benefits such as reduced painkiller use, improved sleep, return to normal daily activities, etc.

It is possible that you may not obtain any health benefits.

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 customer service hours from **9:00 a.m. to 3:00 p.m.,** or visit the Rehabilitation Service itself.

9º ALTERNATIVE TREATMENTS

Among the available alternatives are oral medication, physical therapy alone, and debridement surgery.

10º EXPENSES AND FINANCIAL COMPENSATION

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

11º PERSONAL DATA PROTECTION

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

- For the purposes of using your data:

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

12º BIOLOGICAL SAMPLE COLLECTION

Not required for this study.

13º OTHER ASPECTS

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

You should be aware that you may be excluded from the study if the sponsor or the study researchers deem it appropriate, either for safety reasons (your condition does not respond adequately, any adverse event caused by the study medication, etc.) or because they believe 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 that have been explained to you.

__YES __NO I authorize

Sometimes during the intervention, unexpected findings occur, which may lead to modifications, leading to the use of variations not initially contemplated.

__YES __NO I authorize

Sometimes, images, photos, and videos may be taken. They will be used to better document the case and for educational purposes, and will always remain confidential.

__YES __NO I authorize

If you or any authorized person requires further information, do not hesitate to consult your attending physician or any of the medical staff at the Department treating you.

13º ACKNOWLEDGMENTS

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

Mr./ Mrs…….. Age …….
D.N.I:……NHC……..
Adress……
Phone number……//Mobile……
Sticker

I CONFIRM

That I have been informed by **Dr……** on ……/……/…… (and that I have been given a copy of the information) of the procedure: ……**Hydrodilation** …… and also of the expected benefits and risks involved in performing it (most common complications) and not performing it, as well as the possible alternatives according to the healthcare facilities of this Center.

I understand all the information provided to me, and my questions have been satisfactorily answered.

I CONSENT:

To the physicians of the Physical Medicine and Rehabilitation Service to perform the aforementioned procedure and any necessary additional testing. I understand that in the event of an emergency or for unforeseen reasons, the necessary medical interventions may be performed to keep me alive or prevent harm.

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

Due to incapacity or renunciation of decision-making: Authorizing person (family member or legal guardian) Mr./Ms. ……,with DNI:……as ……

I sign two copies in CÓRDOBA, on …… of …… of ……

Patient's signature **Legal representative's signature** **Physician's signature**

I have decided to REVOKE my consent to carry out the aforementioned procedure.

Patient's signature **Legal representative's signature** **Physician's signature**

(sign only if you revoke prior consent). Date: ……/……/…….