Protocol - Approval 15/1/2026

Efficacy of suprascapular nerve block on the tolerability and efficacy of shoulder hydrodistension in patients with adhesive capsulitis: randomizes clinical trial

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2. Principal Investigator

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Under the supervision of:

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Porto – January 2026

Identification of the Research Unit

Physical Medicine and Rehabilitation Service of the Local Health Unit of São João, EPE

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3. Scientific justification and context

Adhesive capsulitis of the shoulder is a frequent pathology, characterized by pain and progressive limitation of joint mobility, with a significant impact on the quality of life and functionality of patients (1). Shoulder joint hydrodistension is considered one of the treatments of choice, demonstrating effectiveness in reducing pain and improving range of motion. However, the procedure can be painful, which may limit its tolerability and potentially the therapeutic aggressiveness required for effective capsular distension (2, 3).

Suprascapular nerve block, using local anesthetics such as ropivacaine, is a known technique for controlling shoulder pain (4, 5). Its use prior to hydrodistension may:

• Reduce pain during the procedure

• Improve patient tolerance

• Allow greater capsular distension

• Potentially improve clinical outcomes and prognosis

To date, there is limited and heterogeneous evidence on the impact of this block as an adjunct to hydrodistension, justifying the performance of this clinical trial.

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4. Study Objectives

Main Objective

To evaluate the evolution of shoulder pain and mobility in patients with adhesive capsulitis undergoing hydrodistension, with or without suprascapular nerve block.

Pain will be assessed using the Numerical Pain Scale (NRS), and shoulder mobility will be assessed by goniometry of joint ranges of motion.

Assessments will be conducted at three points in time:

• Before the procedure (baseline)

• 1 month after the procedure

• 3 months after the procedure

Secondary objectives

To evaluate the impact of the intervention on psychological, functional, and quality of life dimensions, namely:

• Anxiety and depression, assessed using the Hospital Anxiety and Depression Scale (HADS)

• Kinesiophobia, assessed using the Tampa Scale for Kinesiophobia

• Health-related quality of life, assessed using the EQ-5D-5L

• Upper limb functionality, assessed using the QuickDASH and the Shoulder Pain and Disability Index (SPADI)

These variables will be assessed at two points in time:

• Baseline

• 3 months after the procedure

Additionally, the need for physiotherapy and its duration after the procedure will be evaluated.

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5. Study Design

• Prospective clinical trial

• Randomized

• Two parallel arms

• Open-label

• Single intervention

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6. Study Population

Inclusion Criteria

• Adults ≥ 18 years

• Clinical diagnosis of adhesive capsulitis of the shoulder

• Persistent pain and functional limitation despite initial conservative treatment

• Ability to understand and sign informed consent

Exclusion Criteria

• Known allergy to ropivacaine or methylprednisolone

• Active local or systemic infection

• Uncontrolled coagulopathy or anticoagulation

• Recent prior surgery of the affected shoulder

• Neurological disease affecting the upper limb

• Pregnancy

Sample size (calculation and assumptions)

Proposed primary endpoint: pain and mobility 3 months after hydrodistension (Numerical Pain Scale, NRS 0–10).

Clinical hypothesis: suprascapular nerve block reduces pain during the procedure.

Assumptions for calculation (conservative and clinically plausible):

• Clinically relevant minimum difference (Δ): 2 points on the VAS

• Standard deviation (SD): 2.5 (typical variability in procedural pain)

• Two-tailed test, $\alpha = 0.05$; Power $(1-\beta) = 80\%$

Result of the calculation (comparison of means, 2 groups):

• Approximately 25 participants per group are needed (total 50)

Adjustment for losses/dropouts (≈15%)

• 25 / (1−0.15) ≈ 29.4 → rounding: 30 per group

• Proposed final sample size: 60 participants (30+30)

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7. Randomization

Participants will be randomly assigned in a 1:1 ratio to:

• Control Group: Isolated hydrodistension

• Intervention Group: Suprascapular nerve block followed by hydrodistension

Randomization will be performed using a previously generated random sequence.

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8. Interventions

8.1 Shoulder Hydrodistension (both groups)

Performed anteriorly, with intracapsular injection of:

• 20 ml of saline solution

• 4 ml of ropivacaine

• 40 mg of methylprednisolone

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8.2 Suprascapular Nerve Block (intervention group)

Performed prior to hydrodistension, consisting of an injection of:

• 5 ml of ropivacaine

The block will be performed in the suprascapular notch, on the posterior aspect of the shoulder, according to a standardized technique.

There will be no sham intervention.

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9. Concomitant Treatments

Physiotherapy after the procedure is permitted and not restricted by the protocol. In general, the duration of physiotherapy is expected to be shorter after effective hydrodistension.

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10. Outcome Evaluation

Evaluation Times

Outcomes will be evaluated at three distinct times:

• Before the procedure (baseline)

• 1 month after the procedure

• 3 months after the procedure

Pain during the procedure will be evaluated exclusively at the time of the clinical act.

Primary Outcome

• Pain and mobility, assessed using the Numerical Pain Scale (NRS, 0–10), 3 months after hydrodistension.

Pain

• Shoulder pain at rest and/or with movement, as assessed by the Numerical Pain Scale (NRS)

• Assessed at baseline, 1 month, and 3 months

Shoulder Mobility

• Assessment of joint range of motion (flexion, abduction, external rotation, and internal rotation), measured by goniometry

• Assessed at baseline, 1 month, and 3 months

Secondary Outcomes

Shoulder and Upper Limb Functionality

• Shoulder Pain and Disability Index (SPADI)

• Quick Arm, Shoulder, and Hand Disabilities (QuickDASH)

• Assessed at baseline and at 3 months

Health-Related Quality of Life

• Assessed using the EQ-5D-5L

• Assessed at baseline and at 3 months

Psychological Dimension

• Anxiety and depression, assessed using the Hospital Anxiety and Depression Scale (HADS)

• Kinesiophobia, assessed using the Tampa Scale for Kinesiophobia

• Assessed at baseline and at 3 months

Physical Therapy

• Need for physical therapy after the procedure (yes/no)

• Duration of physical therapy, measured in number of sessions or weeks of treatment

Safety

• Systematic recording of adverse events, including:

o Prolonged pain

o Hematoma

o Infection

o Transient or persistent neurological deficit

o Adverse reactions to the drugs used

Adverse events will be classified according to severity, causal relationship with the procedure, and need for additional intervention.

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11. Safety and Risks

Risks of hydrodistension

• Transient pain

• Hematoma

• Infection (rare)

• Adverse drug reactions

Additional risks of suprascapular block

• Local pain or discomfort

• Hematoma

• Transient numbness or weakness of the shoulder

• Accidental vascular puncture

• Adverse reactions to ropivacaine

• Nerve injury (extremely rare)

All procedures will be performed by an experienced professional, respecting safety and asepsis standards.

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12. Expected Benefits

• Possible reduction of pain associated with the procedure

• Improved tolerability of hydrodistension

• Potential improvement in clinical outcomes

• Contribution to scientific knowledge Direct individual benefit is not guaranteed.

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13. Ethical Considerations

• Participation is voluntary

• Participants may leave the study at any time without clinical detriment

• The study complies with the principles of the Declaration of Helsinki

• Written informed consent will be obtained before any procedure

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14. Data Protection and GDPR

Data will be processed in accordance with the GDPR

Participants will be identified by code

Only the research team will have access to identifiable data

Data will be used exclusively for scientific purposes

Participants may exercise their legal rights over the data at any time

The anonymity and confidentiality of participants will be safeguarded. The patient will be entered without any reference to their name. The participant number will correspond to the clinical information in a separate database, which will only be used for the proposed purpose, after supervision by Master João Paulo Castro and the service director. For analysis purposes, the participant number will be deleted.

All information entered into the database will be recorded in the medical record.

Rules of Ethical Conduct and Good Practices will be observed to ensure compliance with the precepts of the Declaration of Helsinki, the Convention on Human Rights and Biomedicine, the guidelines of the Council for International Organizations of Medical Sciences, and the Guide to Good Clinical Practices.

15. Data Management and Preservation

Data will be stored in a secure physical and/or digital medium for the legally required period and subsequently destroyed.

Patient characterization will be performed, including demographic data, clinical symptoms and associated comorbidities, as well as a description of the surgical techniques used and adverse events that occurred (Appendix 1).

Data collection will be carried out by Master João Paulo Castro, through clinical interviews and consultation of patient records.

Statistical data processing will be performed by Master João Paulo Castro. According to the General Data Protection Regulation (GDPR), data collection will be carried out through registration in a protected Excel spreadsheet, and no patient identification data will be transferred. Each participant will be uniquely identified by a code number, which will be subsequently deleted.

The data will be exported in .xls and .sav formats, compatible with appropriate statistical software, i.e., R, SPSS, Stata, and Microsoft Excel.

16. Funding and Conflicts of Interest

The study does not involve external funding or known conflicts of interest.

No additional costs are foreseen for the Local Health Unit of São João, EPE, beyond the usual study and provision of materials recommended for the treatment of the aforementioned pathologies.

There will be no abuse of hospital resources or any others, which will be determined by the management of the Physical Medicine and Rehabilitation service.

17. Dissemination of results

The results may be presented at scientific conferences and published in indexed scientific journals with an impact factor, always guaranteeing the anonymity of the participants.

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18. Schedule (operational estimate)

Total estimated duration: ~12 months

1. Preparation and ethical approval (Months 0–2)

• Submission to the Ethics Committee and response to any requests for clarification

• Final versions: Information/Consent Sheet, CRF (case report form) and database

2. Recruitment and inclusion (Months 3–8)

• Consecutive screening of eligible patients in consultation/referral

• Randomization and performance of the procedure (block +/− hydrodistension)

3. Clinical follow-up (Months 3–10)

• Standardized post-procedure assessments at defined times (D0, 1 month and 3 months)

4. Statistical analysis and writing (Months 10–12)

• Closing the database, final analysis, submission to congress/journal

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