PARTICIPANT INFORMATION SHEET

Title:
ESTABLE: Shoulder Stability Study Using the Latarjet Procedure with Suture Tape Cerclage versus Screw Fixation

Principal Investigators, Department and Institution:
Dr. Raul Barco Laakso and Dr. Juan Ameztoy Gallego
Department of Orthopaedic Surgery and Traumatology
Hospital Universitario La Paz

Version Number and Date:
Version 2 – September 9, 2025

Introduction

You are being invited to participate in a clinical research study. Our intention is to provide you with clear and sufficient information so that you may decide whether or not you wish to participate. We will clarify any questions that may arise at any time. You may also consult with anyone you consider appropriate before making your decision.

Voluntary Participation

You should know that your participation is entirely voluntary. You may decide not to participate or withdraw your consent at any time without this affecting your relationship with your physician or causing any prejudice to your medical treatment.

Study Description and General Objective

You are being invited to participate in a clinical study designed to compare two surgical techniques used to treat shoulder instability, a condition in which the joint dislocates easily and may cause pain, a feeling of insecurity, and limitations in daily or sports activities.

The surgical procedure used in this condition is called the **Latarjet procedure**, a widely recognized and effective technique for treating shoulder instability. This surgery involves transferring a small fragment of bone from the scapula (called the coracoid process) to the edge of the shoulder socket to improve joint stability.

Traditionally, this bone fragment is fixed to the shoulder using metal screws. However, this technique may involve certain complications, such as hardware discomfort, the need for reoperation to remove the screws, or problems related to graft healing. In recent years, an alternative technique has emerged that uses high-strength suture tapes to fix the bone graft. This method may improve patient tolerance and reduce complications without interfering with bone healing.

The purpose of this study is to compare both techniques to determine whether suture tape fixation is at least as effective as screw fixation in terms of shoulder recovery and function, as assessed by validated questionnaires. Additionally, graft fixation and postoperative complications will be evaluated.

To achieve this, a randomized clinical trial will be conducted. This means that assignment to one fixation method or the other will be determined by chance (similar to flipping a coin), and neither the patient nor the outcome assessor will know which fixation method has been used. The surgical procedure will be identical for all participants; only the method of graft fixation will differ. Both procedures are performed by experienced surgeons and are considered safe. Follow-up will include clinical and radiological assessments for at least 12 months after surgery.

In this study, you will be followed in the same manner whether or not you decide to participate, as treatment and evaluation follow standard clinical practice and your medical care is independent of the study.

If you decide to participate, you will be asked to sign an Informed Consent document. This study will be conducted at Hospital Universitario La Paz, and approximately 80 patients will be included.

Risks and Discomforts Related to Participation

You will not be exposed to any additional or extraordinary risks as a result of participating in this study, since no extra tests beyond routine clinical practice will be performed and the treatment you will receive is well supported by the medical literature.

Potential Benefits

You may not directly benefit from participating in this study. However, we hope that the results will contribute to improved knowledge regarding outcomes in patients undergoing the Latarjet procedure for anterior shoulder instability.

Financial Compensation

Participation in this study will not involve any additional costs for you, nor will you receive any financial compensation.

Contact Information

If you have any future questions regarding the disclosure or use of your medical data, or if you have concerns or complaints about the study or your participation, you may contact:

- **Dr. Juan Ameztoy Gallego or Dr. Raul Barco Laakso**
  Telephone: +34 91 727 70 00 Ext. 47425

INFORMED CONSENT FORM

Title:
ESTABLE: Shoulder Stability Study Using the Latarjet Procedure with Suture Tape Cerclage versus Screw Fixation

Principal Investigators, Department and Institution:
Dr. Raul Barco Laakso and Dr. Juan Ameztoy Gallego
Department of Orthopaedic Surgery and Traumatology
Hospital Universitario La Paz

Version Number and Date:
Version 1 – July 7, 2025

Consent Statement

I (full name) _____, acting on my own behalf,

have read the Participant Information Sheet provided to me and have had the opportunity to ask questions and receive sufficient information about the study. I understand that I may withdraw from the study at any time without providing a reason and without this affecting my medical care.

I understand:

- That the objective of the study is to compare two fixation methods (metal screws versus high-strength suture tape cerclage) that are currently used at Hospital Universitario La Paz.
- That I will be randomly assigned to one of the two groups.
- That I will undergo clinical follow-up and imaging studies for up to 12 months, with the option of follow-up at 24 months, similar to what I would receive if I were not participating in the study.
- That my participation is voluntary and that I may withdraw at any time without affecting my medical care.
- That my personal data will be treated confidentially.

Withdrawal of informed consent will not affect activities already carried out or the use of data obtained prior to withdrawal based on the consent provided.

By providing my data, I confirm that I have read and expressly accepted the processing of such data as described.

I freely agree to participate in this study.

Signed in Madrid on _____ of _____ 20___.

Signature: _____
Investigator Signature: _____
Participant or Legal Representative: _____

CONFIDENTIALITY / DATA PROTECTION

Consent for Research Studies

In accordance with current data protection regulations, I have been informed and expressly consent to the processing of data from my medical record as well as data resulting from my participation in the study:

"ESTABLE: Shoulder Stability Study Using the Latarjet Procedure with Suture Tape Cerclage versus Screw Fixation."

The Data Controller is Hospital Universitario La Paz (including Hospital Carlos III and Hospital Cantoblanco). The Data Protection Officer (DPO) is the Data Protection Committee of the Regional Ministry of Health of the Community of Madrid, located at C/ Melchor Fernández Almagro nº 1, 28029 Madrid, Spain.

The purpose of data processing is to evaluate the clinical outcomes of patients undergoing the Latarjet procedure for anterior shoulder instability.

The legal basis for processing is your consent, as well as Spanish Law 14/2007 of July 3 on Biomedical Research and other applicable legislation.

Your data will be retained for the period necessary to comply with applicable legal obligations and for as long as it remains useful for the purposes for which it was collected, and in any case for at least five years.

Access to my personal information will be restricted to the study physicians, collaborators, authorized study personnel, health authorities, the Hospital Research Ethics Committee, and sponsor monitors and auditors, who will be subject to professional confidentiality obligations and may review the data and procedures when necessary, always in accordance with applicable legislation.

No additional data disclosures will be made except where required by law.

By providing your data, you confirm that you have read and expressly accepted the processing of your personal data as described above.

You may exercise your rights of access, rectification, erasure, objection, restriction of processing, and data portability, where applicable, by written communication to the Data Controller at:

Hospital Universitario La Paz
Paseo de la Castellana 261
28046 Madrid, Spain

You must specify your request and attach a copy of your National ID or equivalent identification document.

You also have the right to file a complaint with the Spanish Data Protection Agency. Withdrawal of consent for data processing will not affect activities already carried out or the use of data obtained prior to withdrawal.

Signed in Madrid on _____ of _____ 20___.

Signed:

Mr./Ms. _____

National ID Number: _____