Research Protocol

Study type
Phase II Clinical Trial

Population
Patients undergoing arthroscopic rotator cuff repair

Intervention
Use of PRP at the repair interface of the posterosuperior rotator cuff

Comparator
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Primary outcome
Healing at six months (Sugaya classification)

Secondary outcomes
Pain (VAS); function (Constant-Murley score and Subjective Shoulder Value); complications

Research question
Does the use of a target dose of PRP affect tendon healing in patients undergoing arthroscopic rotator cuff repair?

Inclusion criteria

- Patients who are candidates for arthroscopic posterosuperior rotator cuff repair at CHUSJ
- MRI follow-up approximately 6 months after surgery
- Signed informed consent

Exclusion criteria

- Previous surgery on the ipsilateral shoulder
- Associated subscapularis tear requiring repair (> Lafosse II)
- Known haematological disease, including platelet disorders

Data to be collected (Appendix)
Data collection time points:

- Preoperatively, on admission to the ward / day surgery (CMS, SSV, VAS, preoperative MRI analysis)
- 1-month postoperative visit (routine): VAS
- 6-month postoperative visit (routine): CMS, SSV, VAS, postoperative MRI analysis, complications

Surgical technique
All patients:

- Biceps tenotomy / tenodesis
- Interscalene block (unless the patient declines)
- Double-row repair (with or without knots in the medial row, at the surgeon's discretion)
- Commercial PRP kit, Arthrex ACP – 4–7 mL of PRP
- Injection at the repair interface
- Analgesic regimen: paracetamol 1 g every 8 h, Skudexa every 8 h, domperidone 10 mg every 8 h, clonixin every 12 h
- Protection of the repair for 4 weeks in an arm sling
- Passive mobilisation from weeks 2–6
- Active mobilisation at weeks 6–8
- Strength training from week 12

Measurement of platelet concentration in the PRP

- Automated cell counter (BK-3100 type), using 10 µL discarded from the PRP obtained

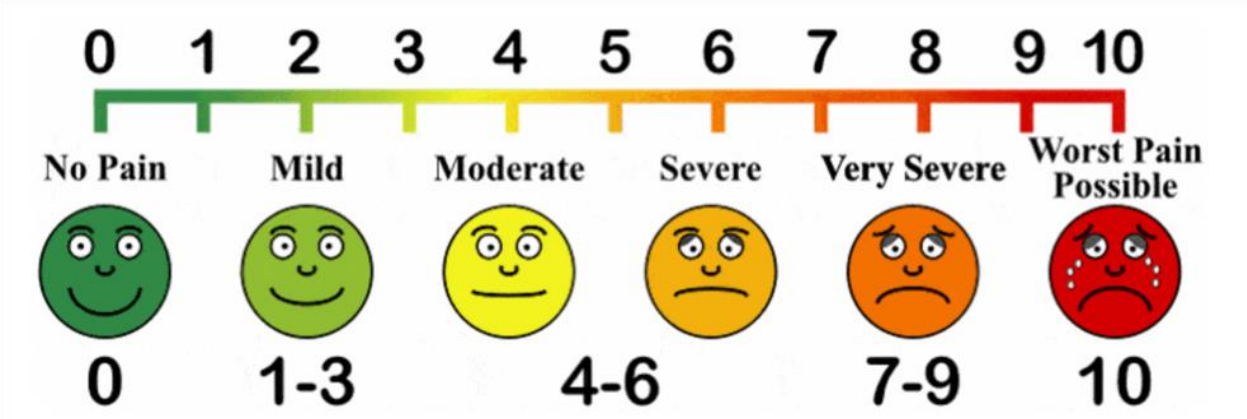
Measurement of baseline serum platelet concentration

- From the preoperative full blood count (routine preoperative work-up)

Outcome measurement

Sugaya:
I – Repaired cuff with sufficient thickness, homogeneously low T2 signal intensity in the tendon
II – Repaired cuff with sufficient thickness, partial high-signal-intensity area within the tendon
III – Insufficient cuff thickness without discontinuity
IV – Minor discontinuity on more than one slice, suggesting a small tear
V – Major discontinuity suggesting a moderate or large tear

VAS



Constant-Murley score (appendix)

Subjective Shoulder Value (SSV):
On a scale from 0 to 100%, where 100% is a perfectly normal shoulder and 0% is a shoulder with no function at all and with pain, how would you rate your shoulder at this moment?

Sample size calculation
The sample size was calculated using tendon healing as the primary outcome. As the Sugaya classification is an ordinal variable with 5 grades, we considered Grades 1–3 as healed and Grades 4 and 5 as not healed. For a phase II clinical trial, the methodology proposed by A'Hern was adopted. This method is used to determine whether a new treatment is likely to reach a basic level of efficacy before it is compared with the standard technique in a larger randomised clinical trial (phase III).

P0 is defined as the level of efficacy indicating that the procedure is clearly ineffective – in this case, the current healing rate after RCR. P1 is the minimum level of efficacy required for the trial to show that this level is plausible given the trial results, and it is greater than P0. The trial therefore tests the null hypothesis H0: $P \leq P0$ against the alternative hypothesis H1: $P \geq P1$, where P is the efficacy shown by the trial results.

Based on previous studies of RCR (rotator cuff repair) without PRP (platelet-rich plasma), a healing rate of 70% was established and will therefore be used as our reference for P0. The treatment would be considered successful if the healing rate reached at least 85%, a 15% difference between P0 and P1. Using an α level of 0.05 and a statistical power $(1 - \beta)$ of 0.8, 49 patients would be required, with a threshold of 40 patients achieving tendon healing to support recommending a phase III clinical trial.