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# Improvement of partial rotator cuff tears with the use of human platelet lysate

**Submission date**
14/01/2020

**Recruitment status**
No longer recruiting

**Registration date**
28/01/2020

**Overall study status**
Completed

**Last Edited**
27/01/2020

**Condition category**
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and study aims
Tendinopathy, also known as tendinitis or tendonitis, is a type of tendon disorder that results in pain, swelling, and impaired function. Supraspinatus tendinopathy is a common source of shoulder pain in athletes that participate in overhead sports (handball, volleyball, tennis, baseball).
Currently, an area that has shown good results for the treatment of tendon disorders is regenerative medicine, with the use of substances that promote and accelerate tissue regeneration. The use of human platelet lysate (hPL) has been shown to be effective for the treatment of orthopedic diseases, but its effectiveness for the treatment of supraspinatus lesions has not been clarified.
The aim of the study is to evaluate the effectiveness of using hPL for the treatment of partial rotator cuff injuries.

Who can participate?
Patients over 40 years old with pain in the shoulder region for over three months, who have not previously had surgical treatment on the shoulder.

What does the study involve?
Participants will receive an injection of hPL into the painful shoulder. A number of tests will be carried out to assess shoulder function and discomfort at baseline at regular intervals for the next six months.

What are the possible benefits and risks of participating?
Benefits: Faster and more effective improvement of symptoms of partial rotator cuff injuries. Early return to work. Decreased function deficit caused by rotator cuff injuries.
Risks:Complications will be analyzed continuously in all outpatient returns, in addition, the patient may seek the urgency and emergency service of our institution if any complications arise. This analysis will be part of the secondary outcome analysis. Complications will be classified as severe when they require an additional procedure not provided for in the initial protocol and mild when they do not. All cases that present complications will be thoroughly evaluated and will be subjected to appropriate treatment as early as possible.

Where is the study run from?
Hospital São Paulo, Brazil

When is the study starting and how long is it expected to run for?
February 2020 to August 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Lauro Pajolli
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# Contact information

### Type(s)
Public

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Protocol serial number
15569019/000005505

# Study information

### Scientific Title
Effectiveness of Using Human Platelet Lysate (hPL) to Treat Supraspinatus Tendinopathy - Clinical Trial

### Study objectives
The use of human platelet lysate is effective and safe for the treatment of supraspinatus tendinopathies.

### Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 19/10/2019, Research Ethics Committee of the Federal University of São Paulo, (Rua Botucatu 740, São Paulo CEP 04023900 SP - Brasil; +551155397162; cep@unifesp.br), ref: 15569019.0.0000.5505

## Study design
Phase two clinical trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Supraspinatus tendinopathies

## Interventions
All patients will be subjected to the collection of a blood sample to quantify platelets, and thus, ensure that they are in accordance with the proposed inclusion criteria. The sample will be fractionated and a portion will be used to prepare the substance to be injected into each one. Whole blood for the purpose of preparing the LPH will be obtained according to routine procedures performed at the Blood Bank (Colsan) and following all current rules for blood donation (RDC34 / 20149 - Consolidation Ordinance No. 5 201710). All donors will sign an institutional consent form.

Initially, local anesthesia will be performed with 1 ml of 2% lidocaine, subcutaneous and intradermal. After waiting 10 minutes, a single experienced researcher will perform the ultrasound examination using a Phillips HD 7 US common 7-10MHz broadband transducer. The patient will sit with the diseased shoulder in hyperextension and with medial rotation with the elbow flexed and the back of the hand on the lower back. The needle will be inserted parallel to the transducer in an oblique plane starting from the lateral region of the shoulder. The beveled side of the needle will be facing the transducer, and the advancement of the needle will be followed in real time by the ultrasound image until the needle tip is viewed into the frame into which the preparation will be injected.

5ml of hPL will be applied directly to the tendon guided by real-time ultrasound imaging, the initial site of application will be the center of the lesion and four points of greatest echogenicity change in the ultrasound image, in case of partial lesions will be applied to the edges of the lesion. rupture and four more points.

Patients will be instructed not to make extreme efforts with the upper limb that had the intervention performed and if they present pain and use paracetamol if they present up to five on the visual analog scale (VAS) 16, and if the pain intensity is higher, use opioid analgesics. up to 8/8 hours 50 mg tramadol. If this occurs, patients are advised to notify the outcome assessor within seven days.

Clinical outcomes will be assessed 10 minutes after the intervention, 1 week, 2 weeks, 4 weeks, 8 weeks, 12 weeks and 6 months. Except for the ultrasound exam, which will be evaluated only after 6 months.

The duration of follow up will be 6 months.

### Intervention Type
Biological/Vaccine

### Phase
Phase II

### Drug/device/biological/vaccine name(s)
Human Platelet Lysate

### Primary outcome(s)
Pain measured using the visual analog scale at baseline and 1, 2, 4, 8, 12 weeks and 6 months after the procedure

### Key secondary outcome(s))
At baseline and 1, 2, 4, 8, 12 weeks and 6 months after the procedure:
1. Shoulder function measured using the Shoulder Pain and Diability Index (SPADI), Neer and Hawkins test, and Quick-Dash
2. The range of motion with digital goniometer (flexion, lateral rotation and medial rotation)
3. Shoulder ultrasound examination (evaluation of tendinopathy size and lesion in millimeters)
4. Complications and adverse effects (according to severity and date of occurrence) measured using patient records

### Completion date
01/08/2020

## Eligibility

### Key inclusion criteria
1. Over 40 years old
2. Pain in the anterolateral shoulder region, without irradiation to the forearm region
3. Pain for more than 3 months of symptoms (measured by Visual Analog Scale)
4. Physical examination (positive Neer test, associated with the Hawkins Kennedy Test and the positive Jobe test) plus magnetic resonance imaging compatible with supraspinatus tendinopathy or partial lesion less than 50%, evaluated by 3 independent evaluators (two orthopedists and a radiologist)
5. Submit and accept the term of clarification and free consent
6. Have not undergone surgery or local injection in the shoulder
7. Agree and sign the free and informed consent form

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
1. Bilateral supraspinatus tendon lesions
2. Presence of fractures, surgeries, infiltrations or previous injuries to the affected shoulder
3. Any condition that is a contraindication to interventions
4. Restriction of passive shoulder range of motion on physical examination
5. Signs of other associated diseases on MRI, except acromioclavicular degeneration
6. Platelets of less than 50,000
7. Contraindication to use any component of the proposed treatments

### Date of first enrolment
01/02/2020

### Date of final enrolment
01/03/2020

## Locations

### Countries of recruitment
Brazil

### Study participating centre
**Hospital São Paulo**
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## Sponsor information

### Organisation
Hospital São Paulo

### ROR
https://ror.org/050z9fj14

## Funder(s)

### Funder type
Other

**Funder Name**
Investigator initiated and funded

# Results and Publications

**Individual participant data (IPD) sharing plan**
The current data sharing plans for this study are unknown and will be available at a later date

**IPD sharing plan summary**
Data sharing statement to be made available at a later date