

# Comparative effectiveness of prolotherapy regenerative injection technique with conventional treatment to treat recalcitrant supraspinatus tendinosis in human subjects

<b>Submission date</b> 01/06/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 05/02/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 31/07/2018	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Shoulder pain is a common complaint occurring in about 15 out of 1000 patients per year in the outpatient primary care setting. Rotator cuff disorders are one of the most common causes of shoulder pain. The treatment for rotator cuff disorders involves activity modification, physical therapy and anti-inflammatory or analgesic medication. If there is little improvement in pain and function, a corticosteroid injection may be used and physiotherapy continued. Prolotherapy is an injection-based treatment used in musculoskeletal conditions. The aim of this study is to assess the effectiveness of prolotherapy compared with conventional therapy of physiotherapy alone by assessing ultrasound changes, function and range of movement before and after treatment.

### Who can participate?

Patients aged 18-65 with supraspinatus tendinosis (shoulder pain) that has not improved after 1 month of conservative treatment

### What does the study involve?

Participants are randomly allocated into two groups. The control group continue conventional physiotherapy and the prolotherapy group receive ultrasound-guided injections and continue physiotherapy. Shoulder function, ultrasound changes and range of movement are assessed before and after treatment.

### What are the possible benefits and risks of participating?

Participants may have faster recovery as a result of the prolotherapy injections. Participants also have close follow up. The injection of prolotherapy is more targeted and less painful as a smaller amount is needed for the injection. There will be some pain due to the injectables which would be similar to the corticosteroid injections which some patients may have received before. Shoulder joint infection is extremely rare and is comparable to the corticosteroid injections (1 in 17,000-50,000).

Where is the study run from?  
University Malaya Medical Center (Malaysia)

When is the study starting and how long is it expected to run for?  
September 2010 to September 2012

Who is funding the study?  
University of Malaya (Malaysia)

Who is the main contact?  
Dr Li Shyan Ch'ng  
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## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
P1055/2010B

## Study information

**Scientific Title**  
Comparative effectiveness of prolotherapy regenerative injection technique with conventional treatment to treat recalcitrant supraspinatus tendinosis in human subjects: a randomised controlled trial

**Study objectives**  
Prolotherapy injections is more effective than conventional therapy (physiotherapy and analgesic) for recalcitrant supraspinatus cuff tendinosis.

**Ethics approval required**  
Old ethics approval format

## **Ethics approval(s)**

Medical Ethics Committee, University Malaya Medical Center, 23/08/2010, ref.: 805.11

## **Study design**

Randomised controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Recalcitrant supraspinatus tendinosis

## **Interventions**

Two study arms which are the prolotherapy regenerative injection therapy group and the control group.

The prolotherapy regenerative injection therapy group receives ultrasound guided prolotherapy injections which consist of a mixture of Dextrose 12% and 0.5% Lignocaine into the area of tendinosis and also standardised regime physiotherapy practiced by University Malaya Medical Center (UMMC).

The control group continue conventional therapy of standardised regime physiotherapy practiced by UMMC physiotherapy and analgesics.

Patients from both groups will have ultrasound changes, Disabilities of the Arm, Shoulder and Hand (DASH) score and range of movement recorded at baseline and at 12 weeks.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

Ultrasound changes such as :

1. Areas and site of hypoechoic tendinosis at area of maximal tendinosis on cross section scanning of the painful region (expressed in mm<sup>2</sup>)
2. The intensity of the area of tendinosis and also the ratio of area of tendinosis with normal tendon area (measured in decibels)
3. Number of focal area of tendinosis
4. Presence or absence of calcification and type of calcification (hard or soft)
5. Presence of tears within the tendon, bursal and articular. Length, site and height of tears are identified in cross section area with most and longest tears noted
6. Presence of periostitis
7. The percentage of Doppler flow within the area of tendinosis measured above: none, less than 50% and more than 50%

8. Presence of subacromial bursitis will also be assessed
9. Dynamic impingement test is also done with distance of between acromion and greater tuberosity at maximal abduction is also measured when impingement is positive

**Key secondary outcome(s)**

1. Disabilities of the Arm, Shoulder and Hand (DASH) Score
2. Physical examination of the range of movement of the shoulder

**Completion date**

01/09/2012

**Eligibility****Key inclusion criteria**

1. Age 18 to 65 years
2. Able to understand completely the study procedure
3. Symptomatic tendinopathy > 6 months
4. Failure of the following conservative modalities: relative rest, physiotherapy, non-steroidal anti-inflammatory drugs and two corticosteroid injection

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Autoimmune Diseases such as Rheumatoid Arthritis etc
2. Patients on anticoagulant such as Warfarin, unless written consent is obtained from the attending physician
3. Congenital or Acquired Platelet Dysfunction abnormality/disorder e.g. von Willebrand Disease, Glanzmann Disease etc
4. Haemoglobin level less than 10G/L and/or Platelet count less than 100,000/uL
5. Diabetes
6. Corticosteroid injection within the past 6 weeks
7. Self-reported immuno-compromised status

**Date of first enrolment**

01/09/2010

**Date of final enrolment**

01/09/2012

## Locations

### Countries of recruitment

Malaysia

### Study participating centre

University Malaya Medical Center

Kuala Lumpur

Malaysia

59100

## Sponsor information

### Organisation

University of Malaya (Malaysia)

### ROR

<https://ror.org/00rzspn62>

## Funder(s)

### Funder type

University/education

### Funder Name

Postgraduate Research Fund University of Malaya (Malaysia)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	results				

[Results article](#)

02/07/2018

Yes

No