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

Submission date
01/06/2012

Recruitment status
No longer recruiting

Registration date
05/02/2013

Overall study status
Completed

Last Edited
31/07/2018

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
lishyan@hotmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Li Shyan Ch'ng

Contact details
Univeristy Malaya Medical Center
Biomedical Imaging
Lembah Pantai
Kuala Lumpur
Malaysia
59100
+603 (0)79493930
lishyan@hotmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 analagesic) 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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 mm2)
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

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

Overall study start date
01/09/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

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)

Sponsor details
Institute of Research Management and Monitoring
Kuala Lumpur
Malaysia
50603
+603 (0)79674522
um_research@um.edu.my

Sponsor type
University/education

Website
http://www.ippp.um.edu.my

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type
University/education

Funder Name
Postgraduate Research Fund University of Malaya (Malaysia)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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 article	results	02/07/2018		Yes	No