

Study to compare the effects of steroid injection vs steroid injection and hydrodilatation in the treatment of adhesive capsulitis

Submission date 19/04/2015	Recruitment status Stopped	☐ Prospectively registered ☐ Protocol
Registration date 02/05/2015	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 12/10/2018	Condition category Musculoskeletal Diseases	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Frozen shoulder (adhesive capsulitis) is a common condition affecting 3 in every 100 people. Frozen shoulder occurs due to inflammation (swelling) in the lining of the shoulder joint (capsule), which causes the lining to become scarred. The scar tissue sticks to the bone, restricts shoulder movement and causes pain. Sufferers normally experience the symptoms of frozen shoulder for around 18 to 24 months. Frozen shoulder usually clears up by itself, therefore available treatments are generally aimed at managing the signs and symptoms of the condition while it is active. There are two treatments commonly available to relieve symptoms of frozen shoulder: hydrodilatation and steroid injection. Hydrodilatation describes a treatment where saline solution, steroid and local anaesthetic are injected into the shoulder to expand the lining of the joint that has become restricted. The procedure happens under local anaesthetic (patient is awake but the shoulder is numbed) and takes around 15 minutes. Steroid injection treatment is when a steroid (e.g. corticosteroids) is injected directly into the lining of the shoulder while the patient is under local anaesthetic. Both treatments aim to reduce pain and inflammation, and improve movement in the affected shoulder. At the moment there is very little evidence comparing the two treatments, so it is not clear if one works better than the other. The aim of this study is to test steroid injections and a combined steroid injections-hydrodilatation treatment and compare how well they work at managing pain, reducing inflammation and improving movement in patients with frozen shoulder.

Who can participate?

Adults with frozen shoulder.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) are given steroid injections for the affected shoulder. Those in group 2 (intervention

group) are given combined steroid injections and hydrodilatation treatment. All participants complete questionnaires and attend clinical assessments before treatment, after 6 weeks and then 3 months after treatment.

What are the possible benefits and risks of participating?

The results of this study could lead to an effective form of pain relief for this patient group, which would allow them more mobility in their day to day life. A further benefit is associated with the use of ultrasound guidance when administering the steroid injection, which may contribute to improved accuracy and is not always available in standard treatment. There are no additional risks to participating in this study.

Where is the study run from?

University College London Hospitals NHS Foundation Trust (UK)

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

April 2015 to April 2018

Who is funding the study?

University College London Hospitals NHS Foundation Trust (UK)

Who is the main contact?

Mr C Cobiella

Contact information

Type(s)

Scientific

Contact name

Mr Carlos Cobiella

Contact details

Institute of Sports Exercise and Health

Sports Medicine Clinic

UCLH

170 Tottenham Court Road

London

United Kingdom

W1T 7HA

Additional identifiers

Protocol serial number

14/0669

Study information

Scientific Title

Study to compare the effects of steroid injection vs steroid injection and hydrodilatation in the treatment of adhesive capsulitis: a randomised control trial

Study objectives

Null hypothesis: hydrodilatation has no added benefit over and above the effect of intra-articular steroid injection in improvement of pain and function in the treatment of adhesive capsulitis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES committee South Central - Oxford B, 13/03/2015, ref: 15/SC/0124.

Study design

Randomised control trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Adhesive capsulitis

Interventions

Changes to pain, strength and shoulder range of movement are assessed over a 3 month period following one of two two groups:

Group 1. Steroid injection

Group 2. Steroid injection and hydrodilatation

Intervention Type

Procedure/Surgery

Primary outcome(s)

Assessed prior to intervention, after 6 weeks and then 3 months post-intervention:

1. Oxford Shoulder Score (OSS) patient-based questionnaire
2. Visual Acuity Score (VAS)
3. Range of motion (ROM) tests using video analysis
4. Change in strength tested using an isokinetic machine

Key secondary outcome(s)

Assess patient acceptability of procedural discomfort and satisfaction with results by questionnaire.

Completion date

12/04/2018

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

1. Clinical diagnosis of adhesive capsulitis
2. Normal radiograph of the shoulder
3. Restriction of range of motion compared to unaffected shoulder of at least 30 degrees in 2 of three movements; forward flexion, abduction, and external rotation in neutral measured with a goniometer.
4. Able to give informed consent
5. Diabetic, thyroid or post traumatic (e.g. post dislocation) causes may be included (otherwise slower to recruit numbers).
6. Symptoms for any period of time as long as it can be recorded
7. All patients presenting with adhesive capsulitis should be considered for the trial, but it's the clinician's choice if they wish to offer other treatments.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients unable to complete questionnaires
2. Patients under 18 or over 85
3. Any surgical intervention for adhesive capsulitis already performed
4. Pre-existing major trauma or surgery to the shoulder
5. Patients with known or suspected musculoskeletal infection in affected shoulder
6. Patients with known or suspected malignancy
7. Steroid injection to affected shoulder less than six weeks at time of proposed intervention
8. Patient on oral steroids
9. Azathioprin, other DMD disease modifying drugs and medication taken after the intervention, in the periods of 6 weeks and 3 months.

Date of first enrolment

16/04/2015

Date of final enrolment

09/04/2018

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University College London Hospital
Institute of Sports Exercise and Health
Sports Medicine Clinic
170 Tottenham Court Road
London
United Kingdom
W1T 7HA

Sponsor information

Organisation

Joint Research Office (part of the Research Support Centre) UCL

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University College London Hospitals NHS Foundation Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No