

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

<b>Submission date</b> 19/04/2015	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 02/05/2015	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 12/10/2018	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please contact Jonathan Cairns, Jon.A.Cairns@gmail.com, Institute of Sports Exercise and Health, Sports Medicine Clinic, UCLH, 170 Tottenham Court Road, London W1T 7HA

## 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 measure

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

### **Secondary outcome measures**

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

### **Overall study start date**

09/04/2015

### **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

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

170 patients from the Upper Limb Orthopaedic department at UCLH

### **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**

England

United Kingdom

**Study participating centre****University College London Hospital**

Institute of Sports Exercise and Health

Sports Medicine Clinic

170 Tottenham Court Road

London

United Kingdom

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## **Sponsor information**

**Organisation**

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

**Sponsor details**

1st Floor, Maple House – Suite B

149 Tottenham Court Road

London

England

United Kingdom

W1T 7DN

**Sponsor type**

University/education

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

### Publication and dissemination plan

Peer-review journal publication and presentation of results at sports medicine-related conferences.

### Intention to publish date

01/04/2018

### 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No