ISRCTN11696305 https://doi.org/10.1186/ISRCTN11696305

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

Registration date
02/05/2015

Overall study status
Stopped

Last Edited
12/10/2018

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

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
W1T 7HA

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?
HRA research summary			28/06/2023	No	No