

Hydrodilatation, corticosteroids and adhesive capsulitis: a randomised controlled trial

Submission date 04/10/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/10/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 02/10/2008	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NFR10458

Study information

Scientific Title

Study objectives

The null hypothesis of the study is that corticosteroid injection with or without hydrodilatation are equally effective as treatment of shoulder capsulitis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional Norwegian Ethics Committee in November 2003.

Study design

Single-centre, interventional, open, randomised study comparing the treatment effect of two different treatment regimens.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Adhesive capsulitis of the shoulder

Interventions

Corticosteroid injection with or without a hydrodilatation procedure. Both treatment groups are given the following drugs in each injection:

1. 3 - 4 ml lopromide, Ultravist 300 Schering AG
2. 2 ml triamcinolone acetonide, Kenacort 10 mg/ml Bristol-Myers Squibb
3. 3 - 4 ml bupivacaine hydrochloride, Marcain 5 mg/ml Astra Zeneca

Both groups are given this injection into the glenohumeral joint under fluoroscopic guidance. The difference between the groups is that the hydrodilatation group is given an additional volume of 10 - 20 ml of Ultravist/Marcain under pressure, in order to distend the glenohumeral joint capsule, which is contracted in these patients.

Three injections are given with two-week intervals. This means that the total duration of treatment is 4 weeks, follow-up is at six weeks after the last injection, 10 weeks in total. Adhesive capsulitis is a temporary condition.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Corticosteroid

Primary outcome measure

Improvement in Shoulder Pain and Disability Index, measured 6 weeks after the last of three injections.

Secondary outcome measures

Shoulder range of motion for four different directions of passive and active movements are measured at baseline and then again six weeks after the last of the three injections. The score at follow-up is the outcome measure.

Overall study start date

01/12/2003

Completion date

01/02/2008

Eligibility**Key inclusion criteria**

1. Pain in one shoulder for more than 3 months but less than 2 years
2. Reduction in shoulder range of motion
3. Ability to fill out shoulder self-report form

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

88

Key exclusion criteria

1. Age below 18 or over 70
2. Various contraindications to injection material
3. Restriction in range of motion for reasons other than capsulitis
4. Mental illness
5. Cancer
6. Current medication with corticosteroids

Date of first enrolment

01/12/2003

Date of final enrolment

01/02/2008

Locations

Countries of recruitment

Norway

Study participating centre

Elgfaret 8

Hornnes

Norway

4737

Sponsor information

Organisation

Norwegian Research Council (Norway)

Sponsor details

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Sponsor type

Research council

Website

<http://www.forskningsradet.no>

ROR

<https://ror.org/00epmv149>

Funder(s)

Funder type

Research council

Funder Name

Norwegian Research Council (Norway) (ref: 10458)

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	19/04/2008		Yes	No