Hydrodilatation, corticosteroids and adhesive capsulitis: a randomised controlled trial

Submission date	Recruitment status		
04/10/2007	No longer recruiting		
Registration date 10/10/2007	Overall study status Completed		
Last Edited	Condition category		
02/10/2008	Musculoskeletal Diseases		

[] Prospectively registered

[] Protocol

[] Statistical analysis plan

[X] Results

[] 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 Norges Forskningsrad Postboks 2700 St. Hanshaugen Oslo Norway 0407 post@forskningsradet.no

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