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Hydrodilatation, corticosteroids and adhesive capsulitis: a randomised controlled trial

Submission date
04/10/2007

Recruitment status
No longer recruiting

Registration date
10/10/2007

Overall study status
Completed

Last Edited
02/10/2008

Condition category
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

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))

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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

ROR
https://ror.org/00epmv149

Funder(s)

Funder type
Research council

Funder Name
Norwegian Research Council (Norway) (ref: 10458)

Results and Publications

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