

The effectiveness of shoulder injections

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Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/06/2015	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

Protocol serial number
NTR201

Study information

Scientific Title
Hyaluronic acid versus corticosteroids compared to a placebo in subacromial injections for shoulder cuff impingement

Study objectives

1. In patients with a painful arc, treatment with hyaluronic acid and lidocaine, will give a mean improvement of 70% of their pain at 26 weeks after start of the treatment with subacromial injection as compared to subacromial injection with a placebo and lidocaine that will show a mean improvement of 50% as against pre-treatment situation
2. When these patients are treated with a corticosteroid and lidocaine, the mean improvement of their pain will also be 70% at 26 weeks after start of the treatment with subacromial injection, compared with a placebo and lidocaine that will show a mean improvement of 50% as against pre-treatment situation

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Randomised double-blind placebo-controlled parallel-group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Shoulder disorders, complaints of shoulder, painful arc

Interventions

Patients are randomised into three groups:

- A. Patients receive a subacromial injection with a mixture of lidocaine (8 ml) and 2 ml hyaluronic acid (Ostenil) by a specially trained physician
- B. The same with a mixture of 8 ml lidocaine with Triamcinoloni acetonidum 10 mg/ml (2 ml)
- C. Patients receiving 8 ml lidocaine with 2 ml saline (control group)

Injections can be repeated after 3 and 6 weeks. No co-interventions are allowed up to 12 weeks. Self-pain medication with paracetamol (acetaminophen) is allowed and recorded.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Lidocaine, hyaluronic acid (Ostenil®), triamcinoloni acetonidum, paracetamol

Primary outcome(s)

At 3, 6, 12 and 26 weeks after the inclusion: patient-perceived recovery measured with a Visual Analogue Scale (VAS) expressed as the proportion of patients indicating very large improvement (including full recovery). The Visual Analogue Scale is a line of 10 cm in length, which is taken to represent the continuum of experienced pain. It has been proved to be a simple, sensitive and

reproducible instrument that enables the patient to express the pain in such a way that it can be given a numerical value.

Key secondary outcome(s)

1. Presence of painful arc
2. Range of motion
3. The Constant shoulder Score
4. Patient Specific Disability
5. Shoulder Disability Questionnaire
6. Shoulder Pain Score
7. Functional Mobility Test

The Constant Shoulder Score is a validated assessment system in which subjective as well as objective assessment takes place in a ratio of 35:65 %. The system is divided into subjective measures for pain and daily activities and objective measures for range of motion and power. The assessment system is designed to provide a full functional assessment applicable to different shoulder conditions. The score is calculated by adding the maximum scores of the individual parameters with a maximum of 100 points.

The Patient Specific Disability instrument measures the functional status of the individual patient. For this measurement the patient has to select 3 - 5 complaints in the field of physical activity. The complaints have to be relevant for the individual patient limit the patient in daily or weekly activities. For assessment of these activities a VAS is used. The score is calculated by adding the distance as measured in millimeters of the 3 Visual Analogue Scales.

The Shoulder Disability Questionnaire is a functional status questionnaire for pain and / or limitation of movement in the shoulder area. The past 24 hours are assessed through 16 questions that can be answered with either, yes, no or not applicable. Score is calculated by multiplying the ratio yes : no by 100%.

The Shoulder Pain Score consists of 6 pain symptom questions and an 101 Numerical Rating Scale (NRS 101) in order to assess pain experienced by patients with shoulder pain. The score has been proved to be useful for following the course of the disorder over time and giving an indication when the patient is cured. The score is calculated by adding the score of the six items 4 points maximum for each item and adding the score of the NRS 101 scale (0-9 = 1, 10-39= 2, 40-69=3 and 70-100= 4). The total of this score has a maximum of 28.

The Functional Mobility Test is used as a standardized active motor test in patients with painful shoulder joint disorders.

For the evaluation of patient perceived pain relief and pain relief patterns, patients will be provided with a Pain Diary, with measures based on a daily Visual Analogue Scale (VAS). The use of self-administered pain relief medication will also be recorded in this diary. The use of the Pain Diary will start after administration of the first injection.

Completion date

31/03/2010

Eligibility

Key inclusion criteria

1. Patients 18 years of age and older
2. Consult a physician for pain in the shoulder either at rest or elicited or provoked during movement of the shoulder
3. Must have a painful arc, with or without a disturbed scapulohumeral movement. The diagnosis is subacromial impingement syndrome.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Pain lasting less than 6 weeks
2. Prior injection with corticosteroids last 3 months, less than 100 degrees range of ante-flexion
3. More than 50% restriction of external glenohumeral rotation (compared to the non-affected side)
4. Steroid or lidocaine allergy
5. Pregnancy or supposed pregnancy
6. Dementia
7. (Prior) purulent infection of the shoulder joints
8. Tumour, osteoporosis, rheumatoid arthritis (American College of Rheumatology [ACR] criteria), referred pain from internal organs, or a cervical radicular syndrome as suspected or definite cause for SD
9. Stroke, polyneuropathy, multiple sclerosis, polymyalgia, ankylosing spondylitis (modified NY criteria) as suspected or definite cause for SD
10. Whiplash, prior fractures or surgery of the shoulder, upper limb, neck or thorax
11. Currently receiving (or needing) treatment for serious behavioral, cognitive or psychiatric disorders
12. Not able to complete Dutch questionnaires independently and those who are reluctant to adhere to (allocated) treatments or to complete follow-up will be excluded

Date of first enrolment

22/10/2004

Date of final enrolment

31/03/2010

Locations**Countries of recruitment**

Netherlands

Study participating centre
University Hospital Maastricht
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Sponsor information

Organisation
Care and Public Health Research Institute (CAPHRI) (The Netherlands)

ROR
<https://ror.org/02jz4aj89>

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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	23/10/2014		Yes	No