ISRCTN51511455 https://doi.org/10.1186/ISRCTN51511455

# The effectiveness of shoulder injections

| | | |
|---|---|---|
| **Submission date**<br>20/12/2005 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>20/12/2005 | **Overall study status**<br>Completed | |
| **Last Edited**<br>26/06/2015 | **Condition category**<br>Musculoskeletal Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Ludo I.F. Penning

**Contact details**
University Hospital Maastricht
Department Orthopedic Surgery
P.O. Box 5800
Maastricht
Netherlands
6202 AZ
+31 (0)43 387 5038
lpenn@sort.azm.nl

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
NTR201

## Study information

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

## 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

## Secondary study design
Randomised parallel trial

## Study setting(s)
Not specified

## Study type(s)
Treatment

## Participant information sheet

## 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 measure
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.

## Secondary outcome measures
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 tot assess pain experienced by patients with shoulder pain. The score has been proved tot 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.

### Overall study start date
22/10/2004

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
159

### 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**
Maastricht
Netherlands
6202 AZ

## Sponsor information

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

### Sponsor details
University Maastricht
P.O. Box 616
Maastricht
Netherlands
6200 MD
+31 (0)43 388 2446
e.habets@caphri.unimaas.nl

### Sponsor type
Research organisation

### Website
http://www.caphri.nl/

**ROR**
https://ror.org/02jz4aj89

# Funder(s)

**Funder type**
Not defined

**Funder Name**
Not provided at time of registration

# 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 | 23/10/2014 | | Yes | No |