The effectiveness of shoulder injections.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22148

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Painful arc and cuff impingement
The most typical feature presented by patients with shoulder disorders (SD) is pain in their shoulder when they move their arm. In a very large majority of patients this pain takes the form of a painful arc: pain during a specific range (usually between 90° and 150°) of shoulder abduction, which prevents them to raise their hand above shoulder level. Such a painful arc is believed to originate from cuff impingement. The painful arc is supposed to be caused by an inflammatory reaction. A sustained inflammatory reaction is described to lead to effusion or calcification in the subacromial space. Both effusion and calcification increase the risk for repeated impingement, and thus maintain the condition.

Sponsors and support

Primary sponsor: Academisch ziekenhuis Maastricht
The Research Institute Caphri of the University Maastricht
Source(s) of monetary or material Support: n/a

Intervention

Outcome measures

Primary outcome

At 3 - 6 - 12 - 26 weeks after the inclusion.
The primary clinical outcome measure will be 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. (Huskisson, 1983)

Secondary outcome

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;
and
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. (Constant 1987, 1991, MacDonald 1993)

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 (Beurskens, Köke, de Vet 1996)

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%. (van der Heijden GJ, Leffers P, Bouter LM 2000)

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. (Winters et al. 1996)

The Functional Mobility Test is used as a standardized active motor test in patients with painful shoulder joint disorders. (Westerberg, Solem-Bertoft, 1996)(van der Heijden et al., 1999)

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.

Study description

Background summary

Background:
The painful arc, believed to originate from shoulder cuff impingement is a feature commonly seen among patients with shoulder disorders (SD). An inflammatory reaction is supposed to cause the painful arc. In the clinical guidelines of the Dutch College of General Practitioners SD are treated with low dose Non Steroidal Anti Inflammatory Drugs.
Insufficient pain reduction with these drugs will lead to treatment with subacromial injections. Injections consist of lidocaine and corticosteroids. Although extensive research has been done, the value of the effect of adding corticosteroids to lidocaine can still be questioned.

Methods:
In a randomized clinical trial, conducted at the University Hospital Maastricht, 159 patients will be included. These patients are randomized over three groups:
A. hyaluronic acid and lidocaine;
B. corticosteroids and lidocaine;
C. lidocaine alone. At baseline socio-demographic variables, values of clinical outcome measures and putative prognostic variables, the presence or absence of a positive test of Neer and severity of the painful arc are documented. After inclusion, primary clinical outcome is measured in the Visual Analogue Scale, Constant Shoulder Score, Patient Specific

Disability, Shoulder Disability Questionnaire, Shoulder Pain Score, Functional Mobility Test and a Pain Diary.

Analysis:
Differences between groups with 95% confidence intervals will be calculated for the outcome measures. Influences of prognostic variables and baseline differences are assessed in a multivariate linear regression model.

Objective:
It is our objective to achieve a better understanding in the value of addition of corticosteroids to lidocaine and the use of hyaluronic acid in SD. We also would like to give the painful arc and test of Neer a more prominent place in the assessment of SD.

Study objective

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 pretreatment 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 pretreatment situation.

Intervention

Patients are randomized 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.

Contacts

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Eligibility criteria

Inclusion criteria

Eligible are patients of 18 years of age and older, who consult a physician for pain in the shoulder either at rest or elicited or provoked during movement of the shoulder. They must have a painful arc, with or without a disturbed scapulohumeral movement. The diagnosis is subacromial impingement syndrome.

Exclusion criteria

Pain lasting less than 6 weeks;
prior injection with corticosteroids last 3 months, less than 100 degrees range of ante flexion;
more than 50% restriction of external glenohumeral rotation (compared to the non-affected side);
steroid or lidocaine allergy; pregnancy or supposed pregnancy; dementia;
(prior) purulent infection of the shoulder joints;
tumor, osteoporosis, rheumatoid arthritis (ACR criteria), referred pain from internal organs, or a cervical radicular syndrome as suspected or definite cause for SD;
stroke, polyneuropathy, multiple sclerosis, polymyalgia, ankylosing spondylitis (modified NY criteria) as suspected or definite cause for SD;
Whiplash, prior fractures or surgery of the shoulder, upper limb, neck or thorax;
currently receiving (or needing) treatment for serious behavioral, cognitive or psychiatric disorders.
Finally, patients who are 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-10-2004
Enrollment:	159
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL165
NTR-old	NTR201
Other	: N/A
ISRCTN	ISRCTN51511455

Study results

Summary results
N/A