The effectiveness of shoulder injections.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22148

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

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.

Ondersteuning

Primaire sponsor: Academisch ziekenhuis Maastricht
The Research Institute Caphri of the University Maastricht
Overige ondersteuning: n/a

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	22-10-2004
Aantal proefpersonen:	159
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A