"Is a simultaneaus intervention of triamcinolon injections with standardized isometric exercises more effective compared to the usual care according to the NHG standard in patients with shoulder complaints.
A prospective, singel blind, randomized clinical trial."

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON29758

Source
ToetsingOnline

Brief title
Investigation of the efficacy of shoulder injections

Condition

- Tendon, ligament and cartilage disorders

Synonym
"impingement subacromial" "tendinitis"

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: "triamcinolon injections" "NHG standard" "exercises" "efficacy"

Outcome measures

Primary outcome

The primary outcome is the change in pain in rest, during activities or during

the night of the last 24 hours, between baseline and 78 weeks.

Secondary outcome

Change compared to the baselien assessments of:

- DASH questionnaire,

- SF36 questionnaire,

- Analgetica use,

- Participant rated improvement,

- Range of Motion maesurements,

- Painful-Arc,

- complications of injections.

Study description

Background summary

In the Netherlands the main part of the patients with shoulder complaints are treated by their general practitioner.
The NHG-standard of 1999 advises two-weakly injections with triamcinolonacetonide subacromial or intra-articulair, dependent of the physical examination of the patient. So far only short-term efficacy of injections with triamcinolonacetonide has been proven by clinical studies. However, so far the long-term efficacy remains unknown. A possible explanation could be that in these studies the treatment period was shorter than 6 weeks, and the protocol never exceeded more than three injection.

Study objective

Therefore the aim of the present study is wheter a simultaneus intervention witht (maximal 5) corticosteroïden/lidocaine injections and exercises for the cuff muscles (both according a standard protocol), have better results than a sequential intervention of first (maximal 3) corticosteroïden/lidocaine injections followed after 6 weeks by exercises (usual care, according to NHG standard) in a group of patients with shoulder complaints.

Study design

In total 205 patients will be recruited of a GPs population of 20,000 patients. Patients will be concealed randomized into 2 groups, group A a simultaneus intervention in which the patients will be injected with a combination of lidocaine and 1 ml Kenacort A40 and at the same time exercises; and group B in which the patient will be injected with a combination of lidocaine and 1 ml Kenacort A40 and after six weeks according to the NHG-standard with exercises.

Intervention

group A a simultaneus intervention in which the patients will be injected with a combination of lidocaine and 1 ml Kenacort A40 and at the same time exercises; and group B in which the patient will be injected with a combination of lidocaine and 1 ml Kenacort A40 and after six weeks according to the NHG-standard with exercises.

Study burden and risks

none

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Those patients with shoulder complaints consulting ther GP with complaints also during the night, and presence of painfull-arc and restricted range of motion.

Exclusion criteria

not signed informed consent form, age under 18 or above 70 year, treatment (exercises or corticosteroid injections) of shoulder complaints during the last 6 months, insufficient command of the Dutch language, spoken and/or written.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-09-2007
Enrollment:	205
Type:	Actual

Ethics review

Approved WMO Date:	13-12-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL12459.078.06