Is a simultaneaus intervention of triamcinolon injections with standardized 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.

No registrations found.

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

Summary

ID

NL-OMON28162

Source
Nationaal Trial Register

Brief title
Investigation of the efficacy of shoulder injections

Health condition

"triamcinolon injections" "NHG standard" "exercises" "efficacy" "shoulder complaints"
"triamcinolon injecties"NHG standaard" "oefeningen"
"effectiviteit" "schouder klachten"

Sponsors and support

Primary sponsor: dr.M.Reijman

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Source(s) of monetary or material Support: none

Intervention

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 baseline assessments of:
1. DASH questionnaire;
2. SF36 questionnaire;
3. Analgetica use;
4. Participant rated improvement;
5. Range of Motion maesurements;
6. Painful-Arc;
7. Complications of injections.

Study description

Background summary

In the Netherlands the preponderance of patients with shoulder complaints are treated by their general practitioner.
The NHG-standard of 1999 advises two-weekly injections with triamcinolonacetonide subacromial or intra-articulair, dependent on the physical examination of the patient. If the shoulder complaints are still present after 6 weeks of fysiotherapy can be considered.
Our hypothesis is that a simultaneous intervention of injections with a combination of lidocaine and 1 ml Kenacort A40 subacromial or intra-articular, in combination with simultaneous fysiotherapy (standardized training program) is more effective compared to the usual care (NHG standard). 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.

In total 205 patients will be recruited. Patients will be concealed randomized into 2 groups, group A; a simultaneous 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.
The procedure of injection will be according to the NHG-standard. The follow-up measurements will be at 6, 12, 26, 52 and 78 weeks.

Study objective

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

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.

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Eligibility criteria

Inclusion criteria

1. Patients with shoulder complaints consulting their GP;
2. Presence of painfull-arc and restricted range of motion.

Exclusion criteria

1. Not signed informed consent form;
2. Age under 18 or above 70 year;
3. Treatment (exercises or corticosteroid injections) of shoulder complaints during the last 6 months;
4. Insufficient command of the Dutch language, spoken and/or written.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2007
Enrollment:	205
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-02-2007
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	NL883
NTR-old	NTR898
Other	: N/A
ISRCTN	ISRCTN75642432

Study results

Summary results
N/A