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.

Gepubliceerd: 09-02-2007 Laatst bijgewerkt: 18-08-2022

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...

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

Samenvatting

ID

NL-OMON28162

Bron
Nationaal Trial Register

Verkorte titel
Investigation of the efficacy of shoulder injections

Aandoening

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

Ondersteuning

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Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with shoulder complaints consulting their GP;

2. Presence of painfull-arc and restricted range of motion.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2007
Aantal proefpersonen:	205
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	09-02-2007
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	NL883
NTR-old	NTR898
Ander register	: N/A
ISRCTN	ISRCTN75642432

Resultaten

Samenvatting resultaten
N/A