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Is a simultaneous intervention of triamcinolon injections with standardised exercises more effective compared to the usual care according to the Dutch College of Family Physicians standard in patients with shoulder complaints? A prospective, single blind, randomised clinical trial

Submission date
26/02/2007

Recruitment status
No longer recruiting

Registration date
26/02/2007

Overall study status
Completed

Last Edited
26/02/2007

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
The aim of the present study is whether a simultaneus intervention with (maximal five) corticosteroid/lidocaine injections and exercises for the cuff muscles (both according a standard protocol), have better results than a sequential intervention of first (maximal five) corticosteroid /lidocaine injections followed after six weeks by exercises (usual care, according to Dutch College of Family Physicians [NHG] standard) in a group of patients with shoulder complaints.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, active controlled, parallel group, single blinded, multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Triamcinolon injections, Dutch College of Family Physician (NHG) standard, complaints of shoulder, exercises, efficacy

Interventions

Group A: the patients will be injected with a combination of lidocaine and 1 ml kenacort A40 and at the same time exercises
Group B: 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 Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Lidocaine, kenacort

Primary outcome measure
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 measures
Change compared to the baseline assessments of:
1. Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire
2. Short Form health survey (SF-36) questionnaire
3. Analgesic use
4. Participant rated improvement
5. Range of motion maesurements
6. Painful-arc
7. Complications of injections

Overall study start date
01/06/2007

Completion date
31/05/2010

Eligibility

Key inclusion criteria
1. Patients with shoulder complaints consulting their General Practitioner (GP)
2. Presence of painful-arc and restricted range of motion

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
205

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

Date of first enrolment
01/06/2007

Date of final enrolment
31/05/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Vrieseweg 157
Dordrecht
Netherlands
3311 NV

Sponsor information

Organisation
Erasmus Medical Centre (The Netherlands)

Sponsor details
Department of Orthopaedics
P.O. Box 2040
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Sponsor type
Hospital/treatment centre

Website

http://www.erasmusmc.nl/

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medical Centre (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration