SIX (Shoulder Injection and eXercise) trial

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

Samenvatting

ID

NL-OMON22406

Bron
NTR

Verkorte titel
SIX

Aandoening

Shoulder complaints

Ondersteuning

Primaire sponsor: Erasmus Medical Center, Department of General Practice
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure is pain and function (SPADI) over 12 months post-randomisation

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
There is an ambiguity in the treatment of shoulder complaints in general practice. Since 1999 the Dutch guideline for shoulder complaints recommends a local corticosteroid injection or referral to physiotherapy for persisting pain. However, more recent evidence found that corticosteroid injections only have a short-term effect on shoulder pain. Furthermore, the Dutch College of General Practitioners emphasize the need of high quality RCT's on the effects of corticosteroid injections and physiotherapy to be able to base their recommendations on high quality evidence.

Objective:
The aim of this study is to assess the (cost-)effectiveness of a local corticosteroid injection versus physiotherapy-led exercise therapy over a 12 month follow-up period. The secondary aims of this study are the (cost-)effectiveness at 6 weeks, 3, 6, and 9 months.

Study design:
An open pragmatic randomized controlled trial with two parallel groups and a follow-up of 12 months after the allocated treatment.

Study population:
Patients who consulted their GP with a new episode of shoulder complaints (n=213).

Intervention:
A local shoulder injection with 40 mg triamcinolone acetonide or a 12-week physiotherapist-led exercise therapy program will be randomly allocated.

Main study parameters/endpoints:
The primary outcome measure is pain and function (SPADI) over 12 months post-randomisation. The secondary outcome is costs (MCQ and PCQ) over 12 months post-randomisation. Other Secondary outcomes include pain and function on other follow-up time points (6 weeks and 3, 6, 9 months after baseline), and global perceived effect, quality of life, side effects, sleep quality, work absence and health care utilisation at all follow-up time points.

Doel van het onderzoek

At the primary end-point (12 months), the clinical effectiveness of physiotherapist-led exercise therapy is hypothesized to be significantly greater than a corticosteroïd injection. With anticipated greater positive effects on work absence (largest costs item due to shoulder pain), the cost-effectiveness of physiotherapist-led exercise therapy is also hypothesized to be superior.

Onderzoeksopzet

6 weeks, 3-6-9 and 12 months

Onderzoeksproduct en/of interventie

Corticosteroïd injection or a 12-week physiotherapist-led exercise therapy

Contactpersonen

Publiek

Erasmus MC
Pieter van Doorn

010-703 37 49

Wetenschappelijk

Erasmus MC
Pieter van Doorn

010-703 37 49

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1) contacted their GP due to a new episode of shoulder pain (ICPC L92 or L08 with unequivocal diagnosis of shoulder complaints);
2) aged 18 years and over;
3) corticosteroid injection or physiotherapist-led exercise therapy is indicated in this patient as recommended by the guideline for shoulder complaints issued by the NHG;
4) signed informed consent form.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1) They are outside the scope of the NHG guideline (eg, shoulder complaints due to recent serious trauma, malignity’s, systemic diseases, neurological or cardial diseases)

2) There is a history of significant shoulder trauma (eg, dislocation, fracture or full thickness tear requiring surgery)
3) They have received a corticosteroid injection or physiotherapy for shoulder complaints in the last 6 months
4) local or systemic infection, after recent vaccination with live attenuated vaccine
5) coagulopathy, use of anticoagulants
6) A history of gastric ulcer
7) Use of CYP3A-inductors
8) Pregnancy
9) Use of oral corticosteroids
10) Allergy to corticosteroids or to anesthetics of the amide type or to the respective preservative (methyl or propyl parahydroxybenzoate or their metabolite para-aminobenzoic acid) or to sulfite;
11) Unable to complete questionnaires in Dutch

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	213
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
Deidentified individual participant data that underlie the results reported in the article will be shared to researcher who provide a methodologically sound proposal. Proposals should be directed to p.vandoorn@erasmusmc.nl. To gain access, data requestors will need to sign a

data access agreement. Data are available beginning 3 months and ending 5 years following article publication. The data will be available on Erasmus MC secured drivers.

Ethische beoordeling

Positief advies

Datum:	26-08-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52854
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8854
CCMO	NL71774.078.20
OMON	NL-OMON52854
OMON	NL-OMON52854

Resultaten