The efficacy of Trigger Finger treatment: a randomised, controlled, prospective clinical multicenter trial.

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We suspect that Trigger Finger treatment by corticosteroid injections will approach the efficiacy which is reached by the 'open' surgical intervention: surgical release of the A1 pulley.

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28338

Bron
NTR

Verkorte titel
N/A

Aandoening

1. Trigger Finger;

2. Stenosing tenosynovitis;

3. Corticosteroid injection;

4. 'open' surgical intervention;

(NLD: Trigger Finger, Stenosing tenosynovitis, Corticosteroïd injectie, 'open' chirurgische ingreep).

Ondersteuning

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Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The treatment of Trigger Fingers will be considered to be succesful when the Plastic Surgeon scores 'grade 0' in accordance with the gradation of Patel and Moradia* to the treated Trigger Finger. Alongside should the following findings be absent: A1 pulley tenderness during palpation, pain during passive extension and tenderness along the flexor tendon on resisted isometric flexion.

*Patel MR, Moradia VJ. Percutaneous release of trigger digit with and without cortisone injection. J Hand Surg (Am) 1997;22A:150-155.

Toelichting onderzoek

Achtergrond van het onderzoek

Several factors can cause a Trigger Finger. There are two accepted treatments for the Trigger Finger nowadays: corticosteroid injections in the affected tendon sheath and surgical release of the affected tendon sheath under local anaesthesia.
It is known that the surgical release is effective, although in comparison with corticosteroid injections it is thorough, expensive and it has higher complication rate.
In this moment there isn't a reliable trial available to determine the effectiveness of corticosteroid injections for the treatment of Trigger Fingers. The very diverse relapse chances after steroidinjections, known from the mostly retrospective trials, are used as an argument to perform a primary surgical treatment.
We would like to investigate the efficiacy of the treatment of Trigger Fingers by means of a reliable, randomised, controlled, prospective multi-center trial at a large-scale with a long term follow-up.
After completion of the trial we will be able to report on the efficiacy of the 'open' surgical treatment as well as the efficiacy of steroidinjections. We will use this result to create a Trigger Finger protocol taking the efficiacy, co-morbidity and costs aspects in account.

Doel van het onderzoek

We suspect that Trigger Finger treatment by corticosteroid injections will approach the efficiacy which is reached by the 'open' surgical intervention: surgical release of the A1 pulley.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

1. Up to two injections triamcinolone acetonide A-10 with six weeks interval between each injection in the A1 pulley of the Trigger Finger;

2. 'open' surgical intervention: surgical release of the A1 pulley of the Trigger Finger.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Capacitated adults to which a treatment for their Trigger Finger will be advised at the outpatient clinic of the plastic surgery in the UMC Utrecht, The Hand Clinic Amsterdam, Diakonessenhuis Zeist, the Mesos Medical Center Utrecht, the St. Antonius Hospital Nieuwegein, the Zuwe Hofpoort Hospital Woerden and the Meander Medical Center Amersfoort.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Incapacitated patients;

2. Patients less then 18 years of age;

3. Women who would like to become pregnant during the period of the trial;

4. Pregnant women;

5. Lactating women.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2008
Aantal proefpersonen:	490
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36372
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1100
NTR-old	NTR1135
CCMO	NL31078.068.09
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON36372

Resultaten

Samenvatting resultaten
N/A