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

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28338

Source
NTR

Brief title
N/A

Health condition

1. Trigger Finger;

2. Stenosing tenosynovitis;

3. Corticosteroid injection;

4. 'open' surgical intervention;

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

Sponsors and support

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Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. The complications which occur after administering the corticosteroid injections in the treatment of adults with Trigger Fingers;

2. The complications which occur after the 'open' surgical intervention in the treatment of adults with Trigger Fingers;

3. The patient characteristics which are associated with a higher risk to develop a Trigger Finger (specific interest for patients with Diabetes Mellitus);

4. The efficacy, in percents, of the 'open' surgical intervention in the treatment of adults with Trigger Fingers when the steroid injections will not be successful;

5. A valid treatment protocol for adults affected with a Trigger Finger and adults affected with a Trigger Finger in a risk group, in which the most efficacy and the lowest complication risk will be found.

Study description

Background summary

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.

Study objective

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.

Study design

N/A

Intervention

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.

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2008
Enrollment:	490
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 36372
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results
N/A