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

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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...

Ethical review	Not approved
Status	Will not start
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON31447

Source
ToetsingOnline

Brief title
Efficacy of Trigger Finger treatment

Condition

- Tendon, ligament and cartilage disorders
- Soft tissue therapeutic procedures

Synonym
snapping finger, Stenosing tenosynovitis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: - Corticosteroid injection, - 'open' surgical intervention, - Stenosing tenosynovitis, - Trigger Finger

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

- The complications which occur after administering the corticosteroid injections in the treatment of adults with Trigger Fingers;
- The complications which occur after the 'open' surgical intervention in the treatment of adults with Trigger Fingers;
- The patient characteristics which are associated with a higher risk to develop a Trigger Finger (specific interest for patients with Diabetes Mellitus);
- 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;

- 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.

Study objective

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 design

Randomised, controlled, prospective, clinical multi-centre trial.

Intervention

1) Apllication of maximal 2 corticosteroïd injections

2) 'open' surgical release A1 pulley

Study burden and risks

The sequence of first injecting after which, in case of an unsatisfactory result will be proceeded to the surgical treatment is preserved in the greater part of the Dutch hospitals.
Up to now there aren't any adverse or serious adverse events reported from either of both treatments which will be investigated.
The extra burden for contestants regarding to not-contestants will be filling in minimal three and maximal five questionnaires which will take an average of ten minutes. We do not expect considerable psychological or physical burden for contestants in comparison with not-contestants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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

- Incapacitated patients;
- Patients less then 18 years of age;
- Women who would like to become pregnant during the period of the trial;
- Pregnant women;
- Lactating women.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	490
Type:	Anticipated

Medical products/devices used

Product type:	Medicine

Brand name:	Kenacort-A 10
Generic name:	Triamcinolone acetonide
Registration:	Yes - NL intended use

Ethics review

Not approved

Date:	08-07-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2008-001315-38-NL
CCMO	NL19294.041.07