# 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...

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|---|---|
| **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

**Public**
Universitair Medisch Centrum Utrecht

Postbus 85500
3508 GA Utrecht
Nederland
**Scientific**
Universitair Medisch Centrum Utrecht

Postbus 85500
3508 GA Utrecht
Nederland

# 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

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| 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 |

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

## Ethics review

Not approved

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| 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 |