

# Are the treatment outcomes of acute and chronic mallet fingers similar?

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To assess whether there is a difference in the outcome in treatment of acute mallet fingers (exist 4 weeks), using the same protocol of intensive follow-up by the 'Handencentrum'.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Tendon, ligament and cartilage disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON38844

### Source

ToetsingOnline

### Brief title

Treatment outcomes of mallet fingers, acute vs chronic .

## Condition

- Tendon, ligament and cartilage disorders

### Synonym

fracture of the fingertip, tendon rupture of the fingertip

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Catharina-ziekenhuis

**Source(s) of monetary or material Support:** Het onderzoek zal tijdens werktijd worden uitgevoerd. Voor het oproepen van de patienten is een medisch student aangetrokken welke teven haar onderzoek stage bij de afdeling plastische chirurgie loopt.

## Intervention

**Keyword:** conservative, mallet finger, splinting, treatment

## Outcome measures

### Primary outcome

The primary endpoint will be the degree of extension (in degrees) of the involved DIP joint six months after the start of therapy.

### Secondary outcome

- To investigate if there are differences in scores of the Michigan Hand Outcome Questionnaire - Dutch Language Version (MHOQ-DLV) and the Patient Rated Wrist/Hand Evaluation - Dutch Language Version (PRWHE-DLV).
- The degree of flexion of the involved joint
- The grabbing strength of the involved hand

## Study description

### Background summary

The standard treatment of acute uncomplicated mallet finger in the Netherlands is often a Stack splint worn for six weeks, possibly followed by hand or physiotherapy. The treatment of chronic mallet finger is however less straight forward. Some choose to treat these injuries by 6 weeks splint therapy followed by physiotherapy, while others opt for surgery by a tenodesmodese. The results of splint therapy in a chronic mallet injuries, according to the literature, are similar to the treatment of an acute malletvinger splint. A prospective study that confirms this, is however still lacking.

### Study objective

To assess whether there is a difference in the outcome in treatment of acute mallet fingers (exist <2 weeks) compared to chronic mallet fingers (exist > 4 weeks), using the same protocol of intensive follow-up by the 'Handencentrum'.

## Study design

The research will be conducted at the 'Handencentrum Eindhoven', the Netherlands. There, they will determine if it is an acute (exist <2 weeks) or chronic (exist >4 weeks) mallet injury. Both will be treated with a similar protocol. After a period of 6 months, the results of this treatment will be evaluated.

## Study burden and risks

The extra burden for participants compared to the \*normal\* treatment is that they need to fill in multiple questionnaires, need to have an additional X-rays taken (of the involved finger and the contralateral finger) and additional out-patient clinic visit is required. The filling in of the questionnaires and additional out-patient visit will require time of the participants. The two additional X-rays will give a radiation dose of <0.01 mSv. The authors are of opinion that this dose is so small that it is to be neglected.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

All patients who report themselves at the 'Handencentrum Eindhoven' with a mallet finger who meet the following criteria:

- Age: between 18 and 65 years
- participants need to be able to make their own decision
- injuries that exist no longer than two weeks (acute)
- injuries that exist longer than four weeks (chronic)

### Exclusion criteria

- Deformities or disease of the involved DIP joint
- Open injury
- Inability to complete splinting therapy (e.g. the likelihood of compliance is low due to psychiatric disorders or beginning Alzheimer disease)

## Study design

### Design

**Study type:** Observational non invasive

Masking: Single blinded (masking used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-07-2013

Enrollment: 34

Type: Anticipated

## Medical products/devices used

Generic name: splint  
Registration: Yes - CE intended use

## Ethics review

Approved WMO  
Date: 20-09-2013  
Application type: First submission  
Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

## 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
CCMO	NL44454.060.13