

# A prospective randomised clinical trial Comparing \*Rotterdam\* splint VS Stack splint in the treatment of tendinous mallet injury, with or without additional hand rehabilitation

Published: 18-03-2009

Last updated: 06-05-2024

This prospective randomised controlled trial makes a comparison between four treatment regiments for mallet injuries without fracture: 1. 6 weeks Stack splint followed by free mobilisation (current standard splint treatment in most of the hospitals)2...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON35246

### Source

ToetsingOnline

### Brief title

Rotterdam spalk VS Stack spalk

### Condition

- Other condition

### Synonym

Extensor tendon injury

### Health condition

Pees letsel

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Medisch Centrum Alkmaar

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** hand therapy, Mallet finger, Rotterdam splint, Stack splint

## Outcome measures

### Primary outcome

At the end of therapy and at 3 months post-therapy, range of motion and extension lag is measured by the same examiner (EA) with a goniometer and compared with the contralateral digit. The skin and nails are examined for deformities and laceration. Stiffness and pain of the digit is noted. Patient Evaluation Measure (PEM) forms are used to assess participants' satisfaction.

### Secondary outcome

nvt

## Study description

### Background summary

In a mallet deformity the distal interphalangeal (DIP) joint is unable to extend fully because of disruption of the extensor apparatus at the base of the distal phalanx. In conservative treatment a mallet splint is used. Currently there is not enough evidence to show which splint is the superior treatment for mallet deformity. The success rate is between 40-72%, depending on splint and treatment regiment used. Hand therapy is also perceived to add to results due to structured rehabilitation program and improvement of patients compliance.

### Study objective

This prospective randomised controlled trial makes a comparison between four treatment regiments for mallet injuries without fracture:

1. 6 weeks Stack splint followed by free mobilisation (current standard splint treatment in most of the hospitals)
2. 6 weeks Stack splint followed by hand therapy with gradual increase of range of motion (ROM).
3. 6 weeks Rotterdam (R) splint followed by free mobilisation
4. 6 weeks Rotterdam (R) splint (adjusted splint, which is used in a few hospitals, e.g. Erasmus University Academic Hospital, with very good results) followed by hand therapy with gradual increase of ROM.

## **Study design**

The patients are prospectively randomly assigned to one of four groups of 40 patients each:

All patients are examined the same day by the first author (E.A.). The extension deficit and ROM of the DIP and PIP joint is measured with a goniometer in a standard way. Patient characteristics like hand dominance, occupation, age, gender, and ROM of the contralateral corresponding digit is measured and noted.

## **Intervention**

Patients are treated with standard therapy (= Stack splint), standard therapy with additional hand therapy, perceived/ presumed improved splint (= R splint) with additional hand therapy, or perceived/ presumed improved splint (= R splint) with additional hand therapy.

## **Study burden and risks**

Patients undergo the same therapy which is already used nowadays. Extra burden for the patient is the extra outpatient clinic visit that has to be done three months post-therapy. Also a short questionnaire should be completed which takes about five minutes time. When the R splint proves better, improvement of therapy for all future patients with mallet type extensor tendon injury can be provided.

## **Contacts**

### **Public**

Medisch Centrum Alkmaar

Wilhelminalaan 12, huisnummer 041  
1815 JD Alkmaar

Nederland  
**Scientific**  
Medisch Centrum Alkmaar

Wilhelminalaan 12, huisnummer 041  
1815 JD Alkmaar  
Nederland

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Tendinous malletfinger

### Exclusion criteria

Fractures, mallet thumb and age < 18 year

## Study design

### Design

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

Control:	Active
Primary purpose:	Treatment

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-03-2009
Enrollment:	160
Type:	Anticipated

## Ethics review

Approved WMO	
Date:	18-03-2009
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO	
Date:	04-05-2010
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

## 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	NL26264.094.09