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 (curent standard splint treatment in ost of the hospitals)2...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	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 asses 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 splints 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 (curent standard splint treatment in ost 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 Academical 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