In search for the optimal treatment for mallet fingers

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The evaluate which treatment of mallet fingers is better, the conventional mallet therapy via the hospital or the personalized treatment with intensive follow up via the handencentrum. This will be investigated for mallet fingers caused by an...

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

Summary

ID

NL-OMON38051

Source
ToetsingOnline

Brief title
The optimal treatment for mallet fingers

Condition

- Tendon, ligament and cartilage disorders

Synonym
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.

Intervention

Keyword: conservative, malllet finger, splinting, treatment

Outcome measures

Primary outcome

Primary Objective:

- To investigate which protocol is most effective in the treatment of mallet finger; the standard protocol or intensive treatment by hand therapists. This will be investigated for mallet fingers due to an extensor tendon rupture as well as the mallet fingers due to an avulsion fracture. The primary end-point will be the degrees of extension of the involved joint, six months after injury.

Secondary outcome

Secondary Objective(s):

- To investigate if there are differences in scores of the Michigan Hand Outcome Questionnaire - Dutch Language Version (MHOQ-DLV) and the Canadian Occupational Performance Measure (COPM)

- To investigate if there is a difference in days away from work

- To investigate if there is a difference patient satisfaction

- To give indication about the costs involved

Study description

Background summary

The standard treatment of an uncomplicated mallet finger in the Netherlands is often a Stack splint worn for six weeks. During the initial consultation at the emergency department patients are informed about their diagnosis and a splint is fitted and applied. Patients are informed that the splint should be worn for

24 hours a day and should only be removed for skin care of the involved finger. During removal of the splint, the finger should be placed on a flat surface to prevent flexion in the distal in DIP joint. During this six week period the patient can return once or twice to the outpatient clinic if preferred for a checkup. After six weeks the splint is removed and patients are advised to slowly start mobilization of the DIP joint.
A potential limitation of this treatment is that patients are, by the limited check-ups and skin care involved, tempted to remove the splint and flectate the DIP joint, disturbing the healing of tendon. Another potential limitation is the mobilization which is not overseen by a professional. This can lead to a too early or too late mobilization, resulting in an extensor lag or flexion limitation, respectively, of the DIP joint.
To overcome these limitations patients we started to refer patient to the hand therapy center. There a custom made splint is applied and check-ups are more frequent. The splint is only removed by the therapist to prevent potential problems of splint removal by the patient themselves. After the six weeks period patient start gradually to mobilize the DIP joint under supervision of the therapist.
At this moment both type of treatments, six week Stack splint and hand therapy center, respectively, take place in the Catharina Hospital Eindhoven, The Netherlands. The received treatment depends on the type of medical specialty by whom the patient is evaluated on the emergency department. Patients with a mallet finger are either seen by the department of plastic surgery or the department of general surgery, this varies per day due to local agreements.

Study objective

The evaluate which treatment of mallet fingers is better, the conventional mallet therapy via the hospital or the personalized treatment with intensive follow up via the handencentrum. This will be investigated for mallet fingers caused by an extensor tendon rupture as well by an avulsion fracture.

Study design

The injury will be investigated whether it is due to an extensor tendon rupture, or an avulsion fracture. Both injuries will be regarded and treated as separate groups. These groups will be analysed via the same research protocol. The study will be a randomized trial comparing the conventional mallet therapy via the hospital and the personalized treatment with intensive follow up via the handencentrum. The study will be performed at the Catharina Hospital, Eindhoven, The Netherlands and the *Handencentrum*, Eindhoven, The Netherlands. Recruitment will be initiated at the emergency department of the Catharina Hospital.

Study burden and risks

The extra burden for participants compared to the *normal* treatment is that they need to fill in multipele 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 filing 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

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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 ER of the Catharina hospital with a malletfinger 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 then two weeks

Exclusion criteria

- Deformities or disease of the involved DIP joint
- Open injury
- Inability the complete splinting therapy (e.g. the likelihood of compliance is low due to psychiatric disorders or beginning Alzheimer disease)
- Mallet fingers caused by an avulsion fracture of the base of the distal phalanx involving more then one third of the joint

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2013
Enrollment:	64
Type:	Anticipated

Medical products/devices used

Generic name:	Splint
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	03-09-2012
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	NL35831.060.12