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

Published: 20-09-2013
Last updated: 23-04-2024

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'.

Ethical review	Approved WMO
Status	Pending
Health condition type	Tendon, ligament and cartilage disorders
Study type	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 tenodermodese. 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 determined 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 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 themselfs 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 desicion
- injuries that exist no longer then two weeks (acute)
- injuries that exist longer than four weeks (chronic)

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

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