Recurrence of Dupuytren*s Disease after treatment with Collagenase Clostridium Histolyticum in the thumb.

Published: 09-11-2015
Last updated: 19-04-2024

To determine the degree of recurrence of contractures in the thumb, caused by Dupuytren'Disease after treatment with CCH

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

Summary

ID

NL-OMON42619

Source
ToetsingOnline

Brief title
Recurrence of DD in the thumb

Condition

- Tendon, ligament and cartilage disorders

Synonym
Dupuytren's Disease, fibromatosis palmaris

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: * (CCH) Collagenase Clostridium Histolyticum, * Dupuytren's Disease, * thumb, *recurrence

Outcome measures

Primary outcome

Contractures are measured with a goniometer. Baseline is the measurement of

ROM in degrees of the extension deficit as measured 30 days after the

injection with CCH . We measure the mean increase of contracture and the

deviation.

Secondary outcome

Not applicable

Study description

Background summary

Between september 2012 and January 2014 12 subjects received an injection with Collagenase Clostridium Histolyticum (CCH) in the thumb to treat contractures caused by Dupuytren's Disease. This took place in the study "A Prospective clinical study on the efficacy of collagenase clostridium histolyticum (CCH) injections in the thumb and first web space contractures in Dupuytren's Disease". The treatment resulted in a significant improvement of Range of Motion in the study group. In this follow-up study we want to determine if and how much what the recurrence there will be in the thumb . Because the disease may develop slowly, we want to do this over a period of 6 years.

Study objective

To determine the degree of recurrence of contractures in the thumb, caused by Dupuytren'Disease after treatment with CCH

Study design

An observational study

Study burden and risks

The subject has to travel to the UMCG to have the position of his thumb measured. Subjects came from all over the country.

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

12 subjects who had CCH treatment in 14 thumbs during previous study.

Exclusion criteria

Subjects who had new treatment of the thumb or first webspace since their treatment with CCH will be excluded

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-02-2016
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	09-11-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL54805.042.15
Other	no number yet