Natural disease progress of Dupuytren's disease

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The primary aim of this study is to gain knowledge on the natural course of Dupuytren's disease, in adults with various Dupuytren disease stages. Secondary aims are: - Gain insight in course after treatment- Determine whether there are risk...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Connective tissue disorders (excl congenital)
Study type	Observational invasive

Summary

ID

NL-OMON46937

Source
ToetsingOnline

Brief title
Natural disease progress of Dupuytren's disease

Condition

- Connective tissue disorders (excl congenital)

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: Dupuytren's disease, Progression

Outcome measures

Primary outcome

The natural course of progression of Dupuytren*s disease, defined as the increase in size of nodules and cords in millimetres and/or increase of total passive extension deficit in degrees and/or a change in echogenicity of the nodules and/or a change in nodule hardness.

Secondary outcome

- Patient questionnaire on functional complaints (URAM-scale DLV)

- presence and course of recurrent disease, defined as the development or change iof nodules and cords in millimetres and/or increase of total passive extension deficit in degrees.

- Echogenicity of the nodules

- Hardness of the nodules

Study description

Background summary

Dupuytren's disease is a progressive fibroproliferative disease. It starts with subcutaneous nodules and pitting in the palm. Later cords appear that connect the nodules and contract the fingers into a flexed position. Usually the deformities are located on the ulnar side of the hand and the fourth digit is more often affected. It can develop and affect a single, but also in multiple adjacent joints, whereby metacarpophalangeal (MP) joints, proximal interphalangeal (PIP) joints and distal interphalangeal (DIP) joints can be involved. It can also affect the subcutaneous tissue and skin.
Some people will only have small lumps, while others will develop a severe contracture of the finger(s), so progression is unpredictable. There is paucity

of knowledge about the natural progression of the disease.

Study objective

The primary aim of this study is to gain knowledge on the natural course of Dupuytren's disease, in adults with various Dupuytren disease stages.

Secondary aims are:
- Gain insight in course after treatment
- Determine whether there are risk factors for progression or recurrence
- Determine at what disease extent / contracture extent patients will report functional complaints
- Determine inter- and intra-observer reliability of the measurements
- Determine whether different methods of measuring contractures yield similar results, and whether this can be derived from each other

Study design

Observational pilot study (longitudinal prospective cohort).

Study burden and risks

This observational study investigates the natural disease progression of Dupuytren*s disease, without interference in the treatment plan. The only measurements are a physical examination of both hands, a short questionnaire at every moment of follow-up and collection of 20 ml of blood once. The potential benefit for participants is that a sudden increase of disease progression or recurrent disease will be noted early and that treatment will not be delayed.
The benefit for patients with DD in general is that our knowledge about natural disease progress enhances and that in the future treatment can be modified based on this new knowledge.
The additional measurement of recurrent disease does not require extra time of the participant, and there are no risks associated with this measurement.
The addition of an extra measurement to determine the intra-observer and interobserver reliability, increases the burden for the patient. However, only a random subsample of the total group will be asked to participate in this additional measurement. They have the opportunity to deny participation. If the patient is not willing to participate in this extra measurement, nothing will change with respect to the standard research protocol.
The ultrasonography and tonometry are not harmful, but participants will have the opportunity to refuse these additional measurements.

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

Presence of primary Dupuytren's disease

Exclusion criteria

Patients who are incapable of giving informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-05-2012
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	16-03-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-07-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-05-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-12-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-04-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO Date:	22-12-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	23-09-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-04-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	03-08-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-03-2018
Application type:	Amendment
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
ClinicalTrials.gov	NCT01923103

Register	ID
CCMO	NL39188.042.11

Study results

Date completed:	20-03-2023
Actual enrolment:	272