Is the weighted genetic risk score associated with Dupuytren disease recurrence?

Published: 06-01-2017
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Primary Objective: To determine whether the wGRS is associated with recurrent DD. Secondary Objective(s): - To determine whether wGRS is associated with the severity of recurrence- To determine whether risk factors for DD are also associated with...

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

Summary

ID

NL-OMON47331

Source
ToetsingOnline

Brief title
Is wGRS associated with DD recurrence?

Condition

- Connective tissue disorders (excl congenital)

Synonym
Dupuytren disease; palmar fibromatosis

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 disease, genetic risk

Outcome measures

Primary outcome

The presence of recurrent Dupuytren disease.

Secondary outcome

Severity of recurrence.

Study description

Background summary

The weighted genetic risk score (wGRS) has shown to be associated with clinical characteristics of DD (i.e. Dupuytren diathesis). It is known that the presence of diathesis features can lead to a more aggressive disease process, with high recurrence. Because of the association between wGRS and diathesis features, it can be expected that a high genetic risk score can also lead to an increased chance of recurrence.
Knowledge about this association can help clinicians to choose the most effective treatment. Patients with a high genetic risk score might benefit more from a more aggressive treatment strategy, reducing the chance of recurrence.

Study objective

Primary Objective:
To determine whether the wGRS is associated with recurrent DD.

Secondary Objective(s):
- To determine whether wGRS is associated with the severity of recurrence
- To determine whether risk factors for DD are also associated with recurrent DD

Study design

Cross-sectional study

Study burden and risks

The burden of participating in this study will be low, because participation requires a time investment of 20 minutes (and time to travel).
All measurements are observational and non-invasive, so participation has no risks.

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

- Dupuytren disease patient
- participant in the GODDAF study (METc2007.067)
- genetic data passed the quality control
- surgical treatment of DD
- written informed consent

Exclusion criteria

- Decisionally incapacitated
- Patients treated for DD with collagenase or radiotherapy

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-03-2017
Enrollment:	677
Type:	Actual

Ethics review

Approved WMO Date:	06-01-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-01-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	04-04-2018
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	NCT02983162
CCMO	NL59032.042.16