Genetic origin of Dupuytren*s disease and associated fibromatosis

Published: 29-05-2007
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The purpose of this study is to further unravel the genetic origin of these individual diseases and their relation at genes level.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON30567

Source
ToetsingOnline

Brief title
GODDAF

Condition

- Musculoskeletal and connective tissue disorders congenital
- Connective tissue disorders (excl congenital)

Synonym
Dupuytren's disease, Ledderhose's disease, Peyronie's disease

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, fibromatosis, Genetics

Outcome measures

Primary outcome

Finding the causative gene(s) of the different fibromatosis. Increasing

understanding of the etiology/pathology of the diseases and there relation to

each other.

Secondary outcome

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Study description

Background summary

Fibromatosis is a pathological diagnosis characterized by local proliferation of fibroblasts and manifested clinically by soft tissue thickening. The most common forms are Dupuytren's disease, Ledderhose's disease and Peyronie's disease. It is thought that these diseases share the same etiology with a hereditary component.
Several candidate susceptibility genes have been proposed lately for Dupuytren's disease and Peyronie's disease.

Study objective

The purpose of this study is to further unravel the genetic origin of these individual diseases and their relation at genes level.

Study design

The different fibromatosis will be studied by means of
1. gene expression analysis; DNA/RNA will be isolated from diseased tissue and blood

2. pedigee analysis; DNA/RNA will be isolated from families (blood)

3. association study; DNA/RNA from blood

Study burden and risks

The burden and risks associated with participation are those of one venapuncture and the application of a questionary.

Participation has no direct benefits for the subjects.

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

Gene expression study:

1.Clinically confirmed diagnosis of Dupuytren*s, Peyronie*s or Ledderhose*s disease
2.Patient for which selective fasciectomy or plaque excision/biopsy is part of standard treatment
3.Evident cord AND node at physical examination (only for patients with Dupuytren*s disease)
4. Age >= 18;Gene expression study Dupuytren controls:
1.Confirmed diagnosis of Carpal Tunnel Syndrome
2.Patient for which carpal tunnel release is part of standard treatment
3.Age >= 18;Gene expression study Peyronie controls:
1.Patient receiving penile prosthesis implants for erectile dysfunction or patient having penis amputation
2.Age >= 18;Pedigree analysis and association study:
1.Clinically confirmed diagnosis of Dupuytren*s disease, Peyronie*s disease or Ledderhose*s disease
2.Having relatives with one of these diseases (only for pedigree analysis)
3.Age >= 18;Pedigree analysis family of proband:
1. Age >= 18;Association study controls:
1.Age >= 18

Exclusion criteria

Gene expression study:
1.Post-surgical recurrence
2.Patients unfit to undergo surgery;Gene expression study Dupuytren controls:
1.Diagnosis of Dupuytren*s, Peyronie*s or Ledderhose*s disease or a positive family history for one of these diseases;Gene expression study Peyronie controls:
1.Diagnosis of Dupuytren*s, Peyronie*s or Ledderhose*s disease or a positive family history for one of these diseases;Pedigree analysis and association study:
None;Pedigree analysis family of proband:
None;Association study controls:
1.Diagnosis of Dupuytren*s disease, Peyronie*s disease or Ledderhose*s disease or a positive family history for one of these diseases

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-06-2007
Enrollment:	600
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	29-05-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-01-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	27-11-2013
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
CCMO	NL16168.042.07