

Percutaneous needle fasciotomy versus limited fasciectomy in Dupuytren's disease

Submission date 29/11/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 06/06/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/06/2011	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
02.0107

Study information

Scientific Title
Percutaneous needle fasciotomy versus limited fasciectomy in Dupuytren's disease: A randomised controlled clinical trial

Study objectives
Now that the armentarium to treat Dupuytren's Disease is increasing, there is a need for comparative studies. We study the 5-year follow-up results of our randomised controlled study

that compared percutaneous needle fasciotomy (PNF) and limited fasciectomy (LF). Primary outcome parameters are results, complications and recurrences. Secondary outcome parameters are patient satisfaction and hand function.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Dutch Medical Ethics Committee approved in July 2002 (ref: 02.0107)

Study design

Single centre single blind randomised active controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Dupuytren's disease

Interventions

Patients were randomised to one of the following treatments

1. Percutaneous needle fasciotomy
2. Limited fasciectomy

All patients were treated only once, within 1 month of inclusion. All were seen in the outpatient clinic 1 week, 6 weeks, 6 months and thereafter yearly until 5 years in the outpatient clinic and examined by a plastic surgeon.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Treatment results: Total Passive Extension Deficit (degrees) assessed postoperatively at 1 week, 6 weeks, 6 months, and then yearly for 5 years
2. Recurrence: Recurrence was defined as an increase of total passive extension deficit of at least 30 degrees compared to the 6 weeks follow-up values in the area previously treated. At the time of registration patients suffering from recurrent disease and treated for recurrence, are still in follow-up.

Key secondary outcome(s)

1. Flexion (Boyes, cm) assessed postoperatively at 1 week, 6 weeks, 6 months, and then yearly for 5 years
2. Sensibility (Semmes-Weinstein) assessed postoperatively at 1 week, 6 weeks, 6 months, and then yearly for 5 years
3. Complications assessed postoperatively at 1 week, 6 weeks, 6 months, and then yearly for 5 years

4. Satisfaction (scale) assessed by questionnaire at 1, 2, 3, 4, 5, 6 weeks, and 6 months, and thereafter yearly until 5 years

Completion date

01/01/2011

Eligibility

Key inclusion criteria

1. Patients with Dupuytren's disease presenting at the Department for Plastic, Reconstructive and Hand Surgery of the Isala Klinieken, Zwolle from August 2002
2. Total passive extension deficit of at least 30° in the metacarpophalangeal (MCP) joint, proximal interphalangeal (PIP) joint and/or distal interphalangeal (PIP) joint
3. Existence of a clearly defined palmar cord
4. Willingness to participate in this trial. Following counselling written consent was obtained from all patients that entered the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Postsurgical recurrence or extension of the disease
2. Patients who were not allowed to stop their anticoagulants
3. Generally unfit for surgery
4. Patients with a specific treatment modality wish

Date of first enrolment

01/08/2002

Date of final enrolment

01/01/2011

Locations

Countries of recruitment

Netherlands

Study participating centre

Hanzeplein 1
Groningen
Netherlands
9713 GZ

Sponsor information

Organisation

University Medical Centre Groningen (UMCG) (Netherlands)

ROR

<https://ror.org/03cv38k47>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Medical Centre of Groningen (UMCG) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2006		Yes	No