ISRCTN58554745 https://doi.org/10.1186/ISRCTN58554745

# Percutaneous needle fasciotomy versus limited fasciectomy in Dupuytren's disease

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 29/11/2010 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 06/06/2011 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 06/06/2011 | Musculoskeletal Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof Paul Werker

**Contact details**
Hanzeplein 1
Groningen
Netherlands
9713 GZ

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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 Dupuytrens 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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

## 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 measure
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.

### Secondary outcome measures
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

### Overall study start date
01/08/2002

### Completion date
01/01/2011

## Eligibility

### Key inclusion criteria
1. Patients with Dupuytrens 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

### Age group
Adult

### Sex
Both

### Target number of participants
120 patients

### 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)

### Sponsor details
Department of Plastic Surgery
Hanzeplein 1
Groningen
Netherlands
9713 GZ

### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/03cv38k47

## Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
University Medical Centre of Groningen (UMCG) (Netherlands)

## Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### 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 |