A pilot randomized controlled trial comparing the effect of minimal invasive technique vs. standard (dermo)fasciectomy surgery in patients with secondary Dupuytren's contractur on convalescence, contraction correction and recurrence rate.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20615

Source
Nationaal Trial Register

Brief title
Du Ro Trial - 2

Health condition

Secondary/ recurrent Dupuytren's disease

Sponsors and support

Primary sponsor: Erasmus Medical Center - Department of Plastic and Reconstructive Surgery
Source(s) of monetary or material Support: Stichting Coolsingel

Intervention

Outcome measures

Primary outcome

1. Convalescence (in days): VAS, 6 questions (diary);

2. Contracture reduction (in degrees): range motion (in degrees), boyes measure (in cm.), pictures.

Secondary outcome

1. Intervention (Register the anaesthetics drugs administered and vital signs during surgery, no protocol is used; Register the therapy used for PIP joint);

2. Hand sensibility and complications due to intervention: semmes weinstein (5 filaments (2.83; 3.61; 4.31; 4.56; 6.65)), volume (in cm.), DASH;

3. Patient satisfaction (VAS scale);

4. MRI and Echo (selection of the intervention group).

Study description

Background summary

Dupuytren’s disease (DD) is a benign, progressive, fibroproliferative disorder that results in the development of abnormal scar-like tissue in the palmar fascia of the hand. Extension to the digits causes progressive digital flexion contracture[1, 2]. In 2006, Dupuytren’s disease was diagnosed 7048 times in the Netherlands. In total, 5843 DD operations were performed that year (Prismant Informatie Expertise). The treatment of DD mainly consists of surgery. Accepted options for managing diseased skin and fascia are (1) limited fasciectomy, (2) segmental fasciectomy (3) fasciotomy (4) dermofasciectomy. Limited fasciectomy and, if necessary, limited dermofasciectomy are the most often-used techniques[3]. With this technique, full recovery of hand function generally takes 2-3 months. In collaboration with the Miami Hand Center (Roger K. Khouri, MD), we developed a technique in which percutaneous release of fibrotic cords is refined in combination with subdermal fat grafting. Subdermal dissection of the cord is performed by making multiple superficial nicks along the entire cord. The cord then chops, disintegrates and separates from the dermis. This space is filled with fat grafts. This technique should have a shorter convalescence because it is less invasive compared with the conventional techniques. Aim of our study is to compare in patients with a secondary Dupuytren’s contracture the effect of a new percutaneous and lipofilling technique

with standard fasciectomy surgery on convalescence, contracture correction and recurrence rate. We will use the VAS and DASH score and hand function test to measure the recovery of the hand function. This study may provide an insight into a better treatment option for patients with Dupuytren’s contractures and it may lower the costs of treatment by shortening the convalescence.

1. Townley, W.A., et al., Dupuytren's contracture unfolded. Bmj, 2006. 332(7538): p. 397-400.

2. Thurston, A.J., Dupuytren's disease. J Bone Joint Surg Br, 2003. 85(4): p. 469-77.

3. McFarlane, R., D.A. McGrouther, and M.H. Flint, eds. Dupuytren's Disease. 1990, Churchill Livingstone: Edinburgh.

Study objective

The percutaneous and lipofilling technique has a shorter convalescence.

Study design

1. Pre operative: range of motion, VAS, DASH, Semmes & Weinstein, diary, pictures, volume measure, grip force;

2. 2 weeks post operative: range of motion, VAS, Semmes & Weinstein, diary, pictures;

3. 3 weeks post operative: range of motion, VAS, Semmes & Weinstein, diary, volume measure, grip force;

4. 6 months post operative: range of motion, VAS, DASH, Semmes & Weinstein, patient satisfaction, diary, pictures;

5. 1 year post operative: range of motion, VAS, patient satisfaction.

Intervention

1. Intervention: Percutaneous lipofilling technique;

2. Control: (Dermo) fasciectomy surgery.

Contacts

Public
PO BOX 2040
S.E.R. Hovius
Erasmus Medical Center

Department of Plastic Surgery and Hand Surgery
Room HS 505
Rotterdam 3000 CA
The Netherlands
+31 (0)10 703 3407
Scientific
PO BOX 2040
S.E.R. Hovius
Erasmus Medical Center
Department of Plastic Surgery and Hand Surgery
Room HS 505
Rotterdam 3000 CA
The Netherlands
+31 (0)10 703 3407

Eligibility criteria

Inclusion criteria

1. Males and females;

2. Age;

3. Secondary Dupuytren's contracture;

4. PIP> 30º / MCP > 20º;

5. One or more affected diatheses;

6. ASA criteria I, II, and III.

Exclusion criteria

1. > 2 times surgery on affected ray;

2. congenital/trauma in past that affects the affected ray in a way that there is no 0 value;

3. Use of blood thinners that can not be stopped for surgery;

4. ASA IV and V;

5. severe CRPS in the past.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2010
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-02-2010
Application type:	First submission

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
NTR-new	NL2098
NTR-old	NTR2215
Other	Erasmus MC, Rotterdam : MEC 2009-437
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A