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

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The percutaneous and lipofilling technique has a shorter convalescence.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22502

Bron
Nationaal Trial Register

Verkorte titel
Du Ro Trial

Aandoening

- primary Dupuytren's contracture
- Percutaneous lipofilling technique
- (dermo)fasciectomy surgery
- convalescence
- pilot randomized controlled trial

Ondersteuning

Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Convalescence (in days): VAS, 5 questions (diary);
2. Contracture reduction (in degrees): range motion (in degrees), boyes measure (in cm.), pictures.

Toelichting onderzoek

Achtergrond van het onderzoek

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 primary 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.

Doel van het onderzoek

The percutaneous and lipofilling technique has a shorter convalescence.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

1. Intervention: Percutaneous lipofilling technique;

2. Control: (Dermo) fasciectomy surgery.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Males and females;

2. Age;

3. Primary Dupuytren's contracture;

4. PIP> 30º / MCP > 20º;

5. One or more affected diatheses;

6. ASA criteria I, II, and III.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Recurrent Dupuytren's contracture;

2. History of hand surgery on the affected finger(s);

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

4. ASA IV and V.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	24-02-2009
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-03-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1609
NTR-old	NTR1692
Ander register	METC ErasmusMC : 2008-264
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A