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.

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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-OMON20615

Bron
NTR

Verkorte titel
Du Ro Trial - 2

Aandoening

Secondary/ recurrent Dupuytren's disease

Ondersteuning

Primaire sponsor: Erasmus Medical Center - Department of Plastic and Reconstructive Surgery
Overige ondersteuning: Stichting Coolsingel

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Convalescence (in days): VAS, 6 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 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.

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. Secondary 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. > 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2010
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-02-2010
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	NL2098

Register	ID
NTR-old	NTR2215
Ander register	Erasmus MC, Rotterdam : MEC 2009-437
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A