Does CCH work For Dupuytren's disease in the thumb and first web space?

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We hypothesize that treatment with collagenase clostridium histolyticum (CCH) injections will also be effective and show significant improvement in outcomes for patients with DD with contractures of the thumb and first webspace.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28569

Bron
NTR

Aandoening

Dupuytren's Disease

Ondersteuning

Primaire sponsor: University Medical Centre Groningen
Overige ondersteuning: funds from Pfizer for drug

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Reduction in extension deficit to 0-5 degrees 30 days after last injection.

Toelichting onderzoek

Achtergrond van het onderzoek

CCH (Xiapex) is the first effective drug on the market for patients with Dupuytren's Disease. It has been developed in the US and has been accepted as drug for the treatment for Dupuytren's Disease. Treatment is reimbursed in the US. In the meantime the drug has been registered in Europe as well and a request for reimbursement by the insurance is with the CVZ. In the Netherlands the drug is so far only used in training sessions. Prof PMN Werker and Drs M Ruttermann, plastic surgeons in the UMCG, are trainers. To this end several patients were treated In the UMCG with CCH injections in their hand/fingers in the last few months. In all cases a significant reduction in the contracture of the treated finger was achieved .
So far the efficacy of the treatment has not yet been studied for Dupuytren's Disease in the thumb, while at the same time treatment of the thumb with the existing options is more difficult than of the fingers.

Therefore this study intends to investigate whether CCH is a good option for the thumb and first webspace, thereby probably preventing more invasive treatment.

Doel van het onderzoek

We hypothesize that treatment with collagenase clostridium histolyticum (CCH) injections will also be effective and show significant improvement in outcomes for patients with DD with contractures of the thumb and first webspace.

Onderzoeksopzet

1, 7, 30, 90 days and 6 months after injection.

Onderzoeksproduct en/of interventie

For each patient the study will have 2 phases. The first phase will be an open label treatment phase (up to 3 months in duration) while the second phase will be a 6 month follow up phase. A maximum of 3 treatment cycles will be offered to each subject where a treatment cycle consists of an injection with CCH (0,58mg) followed by a thumb extension/abduction procedure 24 hrs later and a 30 day follow up period. A maximum of 3 injections will be allowed into the same cord.
In case patients have an adduction contracture and a flexion contracture, they can choose which cord to treat. Measurements of contractures will be taken with goniometer and polluxohgraphy (2) before injection and at follow- up visits.
Follow-up visits will take place at 1 day after injection, 7 days, 30 days, 90 days and 6 months after the last treatment cycle, whereby objective as well as subjective measures will be used and patient/doctor satisfaction will be determined with the help of questionnaires.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. At least 18 years of age and ≤ 75 years;

2. Presenting with a Dupuytren’s contracture at MCPJ of at least 20° caused by a palpable cord in the thumb, or any adduction contracture of the thumb with palpable cords in first web space;

3. In good health, based upon the results of a medical history and physical examination;

4. Female patients of child bearing potential must use an acceptable method of birth control or be surgically sterilized or be a post menopausal female (i.e. no menses for at least 1 year). A pregnancy test will be performed prior to enrolment in the study in fertile women;

5. Patients who are willing and able to comply with scheduled visits, treatment plan, and other study procedures.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

1. Nursing or pregnant, or planning to become pregnant during the treatment phase;

2. On an investigational drug within 30 days prior to the first dose of CCH;

3. Received a treatment on the selected joint, within 90 days of enrolment in the study, for Dupuytren’s contracture including needle aponeurotomy or any surgical procedure;

4. Patients with a known systemic hypersensitivity to collagenase or any of the other product excipients;

5. On anticoagulant medication or has received anticoagulant medication (except aspirin less than 150mg daily) within 7 days before the first injection;

6. Has any clinically significant medical history or condition(s), including conditions that affect the hands that would, in the opinion of the investigator, substantially increase the risk associated with the subject’s participation in the protocol or compromise the scientific objectives of the study;

7. Has a chronic muscular, neurological or neuromuscular disorder that affects the hands;

8. Other severe acute or chronic medical or psychiatric condition or laboratory abnormality that may increase the risk associated with study participation or may interfere with the interpretation of study results and in the judgement of the investigator, would make the subject inappropriate for entry into this study;

9. Has jewellery on the hand to be treated that cannot be removed.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2012
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL3115
NTR-old	NTR3264
Ander register	ABR : 39032
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A