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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28569

Source
NTR

Health condition

Dupuytren's Disease

Sponsors and support

Primary sponsor: University Medical Centre Groningen
Source(s) of monetary or material Support: funds from Pfizer for drug

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Goniometry and pollexography will be used to measure baseline and 1, 7, 30 and 90 days and 6 months after last injection for mean change in range of motion from baseline - degrees;

2. Change in “Patient and physician global assessment of treatment satisfaction” from baseline and 7, 30 and 90 days and 6 months after injection, whereby investigator and patient will complete a brief set of questions;

3. Change in outcome of PRWHE DLV (Patient rated wrist/hand evaluation Dutch language version (37)) from baseline and 7, 30 and 90 days and 6 months after injection whereby the patient will fill in the questionnaire;

4. Photographs will be taken of the diseased hand, during screening and at 30 and 90 days and 6 months.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

Public
Hanzeplein 1
M. Dreise
Groningen 9700 RB
The Netherlands
+31 (0)50 3610269
Scientific
Hanzeplein 1
M. Dreise
Groningen 9700 RB
The Netherlands
+31 (0)50 3610269

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2012
Enrollment:	15
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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

Study results

Summary results
N/A