

A prospective clinical study on the efficacy of collagenase clostridium histolyticum (CCH) injections in the thumb and first web space contractures in Dupuytren's Disease

Published: 22-05-2012

Last updated: 26-04-2024

To evaluate the effectiveness of CCH as treatment for Dupuytren's contracture in the thumb and first web space by assessing pre- and post treatment extension deficit and adduction contracture.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Connective tissue disorders (excl congenital)
Study type	Interventional

Summary

ID

NL-OMON37768

Source

ToetsingOnline

Brief title

The efficacy of CCH in the thumb and first webspace in Dupuytren's Disease.

Condition

- Connective tissue disorders (excl congenital)

Synonym

Dupuytren's Disease, Fibromatosis palmaris

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Pfizer, Pfizer pays for the study

Intervention

Keyword: CCH, Dupuytren's Disease, First webspace, Thumb

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) 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

To evaluate the effectiveness of CCH as treatment for Dupuytren's contracture in the thumb and first web space by assessing pre- and post treatment extension deficit and adduction contracture.

Study design

A prospective clinical trial

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.

Study burden and risks

Risks: Collagenase injections and manipulation are associated with mild to

moderate adverse events, such as bruising, pain and swelling and rupture of the skin. This mostly resolves without intervention in around 14 days.

Benefits: It seems likely that patients do not have to undergo invasive surgery with admission in the hospital. They heal faster, can return to their activities quicker and do not need physiotherapy after the treatment. Regular follow-up/check up visits after treatment will make sure that alternative treatment is offered, in case the CCH injections do not have the expected results.

Contacts

Public

Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Scientific

Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- At least 18 years of age and ≤ 75 years.
- Presenting with a Dupuytren's contracture at MCPJ of thumb of at least 20° caused by a

palpable cord, or any adduction contracture of the thumb with palpable cords in first web space.

- In good health, based upon the results of a medical history and physical examination.
- 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.
- Patients who are willing and able to comply with scheduled visits, treatment plan, and other study procedures.

Exclusion criteria

- Nursing or pregnant, or planning to become pregnant during the treatment phase.
- On an investigational drug within 30 days prior to the first dose of CCH.
- 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.
- Patients with a known systemic hypersensitivity to collagenase or any of the other product excipients.
- On anticoagulant medication or has received anticoagulant medication (except aspirin less than 150mg daily) within 7 days before the first injection.
- 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.
- Has a chronic muscular, neurological or neuromuscular disorder that affects the hands.
- 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.
- Has jewellery on the hand to be treated that cannot be removed.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 10-09-2012
Enrollment: 15
Type: Actual

Medical products/devices used

Product type: Medicine
Brand name: Xiapex
Generic name: Collagenase Clostridium Histolyticum
Registration: Yes - NL outside intended use

Ethics review

Approved WMO
Date: 22-05-2012
Application type: First submission
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO
Date: 14-06-2012
Application type: First submission
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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
Other	3300
EudraCT	EUCTR2012-000516-28-NL
CCMO	NL39032.042.12