

Collagenase (Xiapex) Consent Form updated Sept 2015



PATIENT DETAILS



NAME OF TREATMENT

- Injection of Collagenase (Xiapex)

DIGIT TO BE INJECTED

PURPOSE OF TREATMENT

- To improve deformity
- To avoid surgery
- To remove disease

RISKS

There are two **very rare** but potentially very serious problems:

- **Allergic reaction:** There is a theoretical risk of anaphylactic shock (ie sudden collapse with airway obstruction and circulatory collapse). This is exceedingly unlikely and has never been reported with the drug. Nevertheless, Adrenaline (the antidote to this) is kept immediately available when the drug is given.
- **Tendon rupture:** Collagenase will damage tendons if inadvertently injected too deeply. For this reason, it is only administered by trained hand surgeons.

There are two **common** (greater than 1:10) risks which settle within two to three weeks at most

- **Skin tear**
- **Blood Blister**

According to the data sheet, the following are further risks:

Very common side effects, affects more than 1 user in 10

- Reactions at the injection site like bleeding, pain, swelling, tenderness and bruising.
- Itching in the hand.
- Feeling of pain in the hand, wrist or arm.

- Swollen or enlarged glands near the elbow or under the arm.
- Swelling in the hand or arm.

Common side effects, affects 1 to 10 in 100

- Joint swelling and pain.
- Burning sensation, partial loss of sensitivity, feeling of “pins and needles” or numbness.
- Dizziness, headache, nausea.

SO THAT YOU ARE FULLY INFORMED, REMEMBER THAT THERE ARE ALTERNATIVES TO XIAPEX: SEE WEBPAGE:

<http://www.ncbi.nlm.nih.gov/pubmed/21382860>

Leave Alone: this is a benign condition and if it does not cause too much trouble you can leave it (although treatment becomes less reliable with greater contracture).

Needle Aponeurotomy: Cheaper, less chance of pain, bruising, skin split, blister but less accurate and higher recurrence. Higher chance (but still rare) of nerve damage.

Surgery: lower recurrence (especially if skin graft) but longer recovery and higher chance of a significant complication (nerve damage, stiffness, wound problems). More expensive. Scarring.

OTHER INFORMATION TO CONSIDER

- Xiapex is often more painful than people expect
- The recurrence rate can be disappointing because not all the disease, nor the cells that form the disease, are removed.

THE CHANCE OF THE DISEASE COMING BACK IS HIGH

The latest research shows that the chance of recurrence is 27% at the MP joint and 56% at the PIP joint at three years and 39%-66% respectively at 5 years. This is probably higher than surgery and lower than needle fasciotomy. You may be disappointed if the disease recurs.

Peimer C, Blazar P, Coleman S, Kaplan T, Smith T, Lindau T. *Dupuytren Contracture Recurrence Following Treatment With Collagenase Clostridium Histolyticum (CORDLESS [Collagenase Option for Reduction of Dupuytren Long-Term Evaluation of Safety Study]): 5-Year Data.* J Hand Surg (Am) 2015;40:1597-1605

- I confirm that I understand the purpose of the treatment and the potential risks
- I confirm that I have studied the Information Sheet downloadable from www.collagenase.co.uk
- I confirm that I may be contacted in future as part of an ongoing research programme into the longer term satisfaction and durability with the treatment.

PATIENT’S AND SURGEON’S SIGNATURE:

NAME (CAPITALS)

DATE

I confirm that I have been through the risks and benefits and alternatives of the Xiapex injection

Professor David Warwick
Date