

Patient consent for clostridium collagenase injection treatment



Background Information

Clostridium collagenase (Xiaflex®) is a TGA approved injectable enzyme for the treatment of Dupuytren's Contracture. The collagenase is injected into the contracting band improving the position of the affected finger.

Compared to traditional open surgery, there is less post-operative pain and faster healing allowing a quicker recovery and earlier return to activities. An alternative treatment is needle fasciotomy, which has similar results to clostridium collagenase treatment after 3 months.

Specific potential complications of clostridium collagenase injection include, but are not limited to: recurrence of the contracture, persistence of the contracture, swelling, bruising, bleeding, infection, skin splitting, fracture, allergic reaction including anaphylaxis (shock), ligament injury, tendon rupture (reported rates of 0.3-0.6%), pulley rupture, complex regional pain syndrome and permanent injury to nerves or arteries. The long term safety of clostridium collagenase treatment is not fully characterised.

In clinical trials 38-70% of patients developed a bruise, contusion or injection site bleed. The safety of clostridium collagenase treatment in individuals who are taking blood thinners (except for low-dose aspirin) is uncertain and may increase the risk of complications.

Frequently reported adverse drug reactions in the clinical trials of clostridium collagenase include: peripheral swelling, bruising, injection site bleeding and reactions, pain, tenderness, itching, lymph node swelling and/or pain, skin laceration and arm pit pain (*see table, right*).

In clinical trials patients required an average of 1.7 treatments, so more than one treatment may be required. Treatments are spaced a minimum of 4 weeks apart.

Consent for clostridium collagenase injection:

I have read the information above and understand the risks and benefits of clostridium collagenase injection. I have had an opportunity to discuss with my doctor any questions I have concerning this procedure.

I am not pregnant. I am not taking blood thinning medications (except low dose aspirin) and have not taken doxycycline antibiotics within the last 14 days. I consent to this procedure.

Adverse reaction ¹	Collagenase (n=249)	Placebo (n=125)
All adverse reactions	98%	51%
Peripheral oedema (swelling)	73%	5%
Contusion	70%	3%
Injection site bleeding	38%	3%
Injection site reaction including inflammation, redness, irritation, pain and heat	35%	6%
Pain in the limb	35%	4%
Tenderness	24%	0%
Injection site swelling	24%	6%
Itching	15%	1%
Lymph node swelling	13%	0%
Skin laceration or tear	9%	0%
Lymph node pain	8%	0%
Redness	6%	0%
Arm pit pain	6%	0%

Signature: _____

Name: _____

Date: / /

¹ Adverse reactions occurring in >5% of patients treated in clinical trials with clostridium collagenase and at a greater incidence than placebo in the placebo-controlled trials through to day 90 after up to 3 injections. This study included 1082 patients who received 2630 injections of clostridium collagenase.