

Study Title: *Local injection of collagenase clostridium histolyticum (XiapexR) for refractory gastrointestinal strictures: an open-label pilot study.*

EudraCT number: *2018-003637-14*

Eudamed number: *Not applicable*

Study protocol code: *AGO/2018/004*

ClinicalTrial.gov identifier: *NCT03898661*

Sponsor: *UZ Ghent*

National Coordinator/ Coordinating Investigator: *Prof. Dr. Pieter Hindryckx*

Funder: *Belgian Society of Gastrointestinal Endoscopy*

Date of report: *04/11/2022*

1. Results

1.1 Subject enrollment and demographics

A total of 2 male patients were recruited in the University Hospital of Ghent.

First inclusion: 10/09/2019

Last patient out: 01/01/2021

1.2 Study specific results

We have study results of only 2 patient due to premature termination of the study.

Patient 1 completed the study protocol and the follow-up. There were no complications. His dysphagia score was 1 for the complete study period. He received only 1 repeat dilatation 95 days after the study drug administration. The dilatation was performed because of impossible passage with a normal gastroscope, not because of an increase in dysphagia symptoms.

Patient 2 had an unexpected serious adverse event (esophageal perforation) shortly after study drug administration. He got operated 2 days after study drug administration.