ISRCTN11791921 https://doi.org/10.1186/ISRCTN11791921

The safety and utility of a novel automated mechanical endoscopic tissue resection tool for endoscopic necrosectomy

Submission date	Recruitment status	[_] Prospectively registered
27/09/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/10/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/01/2021	Digestive System	

Plain English summary of protocol

Background and study aims
Acute pancreatitis is a sudden inflammation of the pancreas. The most common cause of acute pancreatitis is gallstones, other known causes include amongst others alcohol use, trauma, medication and high lipid (fat) levels. In 80% of patients pancreatitis is mild and settles within a week or two. In about 20% of patients the pancreatitis becomes severe. Parts of the pancreas may die (necrose). When the necrosis becomes infected, treatment is virtually always necessary. Infected necrosis is associated with a mortality (death rate) of 20% and many other complications. A lot of studies have been performed to optimize the treatment strategies for these patients. Endoscopic drainage of the abscess and necrosectomy (actively remove the necrotic tissue) have been shown to be effective. However, currently no effective tool is available to remove the necrotic tissue. The aim of this study is to evaluate a novel tool (the EndoRotor) to endoscopically remove necrotic tissue.

Who can participate?
Patients aged 18 and over with acute necrotizing pancreatitis

What does the study involve?
Patients undergo endoscopic drainage and necrosectomy. The only difference is that the necrosectomy is performed using the EndoRotor. Technical success is defined as complete removal of the pancreatic necrosis at the discretion of the treating physician.

What are the possible benefits and risks of participating?
There are no additional risks with participating in this study besides known risks for necrosectomy. Possible benefits include fewer procedures to achieve complete removal of pancreatic necrosis and shortened length of hospital stay.

Where is the study run from?
Erasmus University Medical Center (the Netherlands) and Sana Klinikum Offenbach (Germany)

When is the study starting and how long is it expected to run for?
October 2016 to December 2018

Who is funding the study?
Erasmus University Medical Center (Netherlands)

Who is the main contact?
Dr A.D. Koch

Contact information

Type(s)
Scientific

Contact name
Dr A.D. Koch

Contact details
Erasmus Medical Center
Department of Gastroenterology and Hepatology
Doctor Molewaterplein 40
Rotterdam
Netherlands
3015 GD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MEC-2018-1426

Study information

Scientific Title
Safety and efficacy of the EndoRotor® for endoscopic treatment of patients with acute necrotizing pancreatitis

Acronym
EETAP

Study objectives
The EndoRotor is an effective endoscopic tool for the removal of pancreatic necrosis in patients with acute necrotizing pancreatitis.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Erasmus University Medical Center Ethics Committee, 17/09/2018, ref: MEC-2018-1426

Study design
Prospective multicenter study

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Acute necrotizing pancreatitis

Interventions
Patients (male and female, aged over 18 years) were treated for (infected) necrotizing pancreatitis. Patients underwent transluminal drainage followed by direct endoscopic necrosectomy using the EndoRotor. Details on the procedure with the EndoRotor were identified; duration of the procedure, number of interventions to completely remove necrotic tissue, and procedural complications. Patients were followed during their hospitalization.

Intervention Type
Device

Primary outcome measure
Technical success: this was defined as complete removal of the pancreatic necrosis at the discretion of the treating physician. This was disregarding the number of necessary interventions.

Secondary outcome measures
1. The incidence of complications associated with the endoscopic treatment, evaluated during the procedure and after the procedure during admission
2. Total number of interventions to achieve complete removal of pancreatic necrosis

Overall study start date
01/10/2016

Completion date
01/12/2018

Eligibility

Key inclusion criteria
1. Male and female
2. Aged 18 years or older
3. Acute necrotizing pancreatitis

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10

Key exclusion criteria
Inability to undergo endoscopic treatment due to comorbidity

Date of first enrolment
01/01/2017

Date of final enrolment
27/07/2018

Locations

Countries of recruitment
Germany

Netherlands

Study participating centre
Erasmus University Medical Center
Dr. Molewaterplein 40
Rotterdam
Netherlands
3015 GD

Sponsor information

Organisation
Erasmus University Medical Center

Sponsor details
Erasmus Medical Center
Department of Gastroenterology and Hepatology
Dr. Molewaterplein 40
Rotterdam
Netherlands
3015 GD

Sponsor type
Hospital/treatment centre

Website
www.erasmusmc.nl

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned submission of manuscript to a high-impact peer-reviewed journal.

Intention to publish date
01/01/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr A.D. Koch (a.d.koch@erasmusmc.nl)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	preliminary results	21/02/2020	13/07/2020	Yes	No