

PELstone Study: Pancreatoscopy-guided electrohydraulic lithotripsy for the treatment of obstructive distal main pancreatic duct stones.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27159

Source

Nationaal Trial Register

Brief title

PELstone Study

Health condition

Lithotripsy, Pancreatoscopy-guided, Main pancreatic duct stones, Clinical success
Lithotripsie, ERCP, Stenen, Klinisch succes

Sponsors and support

Primary sponsor: Erasmus University Medical Center

Source(s) of monetary or material Support: Boston Scientific Group

Intervention

Outcome measures

Primary outcome

To investigate the technical success of pancreatoscopy-guided EHL, in case clearance of main pancreatic duct stones, in patients with symptomatic chronic pancreatitis due to obstructive distal main pancreatic duct stones who did not undergo previous endoscopic or surgical treatment.

Secondary outcome

1. To evaluate the clinical success of pancreatoscopy-guided EHL, defined as reduction in pain scores and opiate usage.
2. To evaluate the safety profile of pancreatoscopy-guided EHL.
3. To assess the need for hospitalization for pain and/or a flare of chronic pancreatitis.
4. To evaluate the total number of ERPs with or without repeat pancreatoscopy-guided EHL to achieve total or partial stone clearance (excluding procedures scheduled for dilatation therapy of a concomitant stricture).
5. To evaluate the perceived burden and quality-of-life (QoL).
6. To evaluate health resources utilizations / direct medical costs.

Study description

Background summary

In this non-randomized single center prospective cohort study we investigate the efficacy and safety of pancreatoscopy-guided EHL in patients with symptomatic CP due to obstructive distal main pancreatic duct stones not having undergone previous treatment. The primary endpoint is clinical success.

Study objective

Current treatment of patients with symptomatic chronic pancreatitis (CP) and obstructive main pancreatic duct stones consists of extracorporeal shockwave lithotripsy (ESWL) followed by endoscopic retrograde pancreatography (ERP) to extract the fragmented stones. Pancreatoscopy-guided electrohydraulic lithotripsy has shown potential value in CP patients, but is a novel second-line intervention after failed ESWL, due to the necessity of nonstandard equipment and materials. First line intervention with pancreatoscopy-guided electrohydraulic lithotripsy (EHL) could potentially obviate the need for ESWL in selected patients, reducing patient burden, costs and healthcare utilization.

Study design

Primary and secondary endpoints will be evaluated at day 1, 1 month, 3 months and 6 months after the EHL procedure.

Intervention

Pancreatoscopy-guided EHL, performed with a digital single-operator cholangio-pancreatoscopy system (Spyglass Direct Visualization System) with EHL (Nortech AUTOLITH system).

Contacts

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Eligibility criteria

Inclusion criteria

- Male or female ≥ 18 years old
- Symptomatic chronic pancreatitis with obstructive pancreatic duct stones (> 5 mm), in the head or neck of the pancreas.
- Written informed consent.

Exclusion criteria

- Chronic pancreatitis with obstructive pancreatic duct stones, located in the body or tail of the pancreas.
- History of treatment of pancreatic duct stones with ESWL.
- History of surgical treatment of chronic pancreatitis.
- Pregnancy.
- Inability to provide informed consent.
- Inability to undergo endoscopic treatment due to comorbidity.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-12-2017
Enrollment:	25
Type:	Anticipated

Ethics review

Positive opinion	
Date:	29-11-2017

Application type:

First submission

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
NTR-new	NL6683
NTR-old	NTR6853
Other	METC Erasmus MC : MEC-2017-179

Study results

Summary results

n/a