Pancreatoscopy-guided electrohydraulic lithotripsy for obstructive distal main pancreatic duct stones; a clinical outcome and cost evaluation study.

Published: 21-11-2017
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To 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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Interventional

Summary

ID

NL-OMON47888

Source
ToetsingOnline

Brief title
PELstone study

Condition

- Gastrointestinal stenosis and obstruction

Synonym
chronic inflammation of the pancreas with obstruction of the main pancreatic duct., Chronic pancreatitis with obstructive main pancreatic duct stones

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Bedrijf ,Boston Scientific Cooperation International

Intervention

Keyword: Clinical success, Lithotripsy, Main pancreatic duct stones, Pancreatoscopy-guided

Outcome measures

Primary outcome

The primary endpoint is the technical success rate of pancreatoscopy-guided EHL

(clearance of main pancreatic duct stones).

Secondary outcome

The secondary endpoints include clinical success (reduction in pain scores and

opiate usage), ERCP related complication rates within 30 days of treatment,

number of repeat ERPs for stone clearance, length of hospital stay, perceived

burden and quality of life, and costs.

Study description

Background summary

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 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 objective

To 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.

Study design

Non-randomized single center prospective consecutive cohort study.

Intervention

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

Study burden and risks

The burden of participation is limited since patients with chronic pancreatitis with main pancreatic duct stones are already scheduled to undergo (multiple) ERP(s) preceded by 3 sessions of ESWL. If pancreatoscopy-guided EHL lives up to the promise, based on excellent performance data in the treatment of refractory biliary stones and an outstanding safety profile, it will reduce the number of procedures required for stone fragmentation an clearance and thereby patient burden.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Written informed consent
2. Age equal to or above 18 years (adult)
3. Symptomatic chronic pancreatitis with obstructive pancreatic duct stones (> 5 mm), in the head or neck of the pancreas.

Exclusion criteria

1. Inability to give informed consent.
2. Age less than 18 years of age.
3. Chronic pancreatitis with obstructive pancreatic duct stones, located in the body or tail of the pancreas.
4. History of treatment of pancreatic duct stones with ESWL.
5. History of surgical treatment of chronic pancreatitis.
6. Pregnancy.
7. Inability to undergo endoscopic treatment due to comorbidity.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-12-2017
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Spyglass Direct Visualization System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-11-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-02-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-01-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL60630.078.17