

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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27159

Bron

Nationaal Trial Register

Verkorte titel

PELstone Study

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus University Medical Center

Overige ondersteuning: Boston Scientific Group

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To investigate the technical success of pancreatoscopy-guided EHL, in casu 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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

P.J.F. de Jonge
's Gravendijkwal 230

Erasmus Medisch Centrum Rotterdam, Department of Gastroenterology & Hepatology
Rotterdam 3015 CE
The Netherlands
0628235160

Wetenschappelijk

P.J.F. de Jonge
's Gravendijkwal 230

Erasmus Medisch Centrum Rotterdam, Department of Gastroenterology & Hepatology
Rotterdam 3015 CE
The Netherlands
0628235160

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-12-2017
Aantal proefpersonen:	25
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	29-11-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6683
NTR-old	NTR6853
Ander register	METC Erasmus MC : MEC-2017-179

Resultaten

Samenvatting resultaten

n/a