

Selecting Expected choledocho-Lithiasis patients for EndosCopic Therapy

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About 15% of the patients with gallstones detected by EUS will pass the stones spontaneously into the bowel. This means that in these 15% unnecessary ERCP can be avoided.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21673

Bron

NTR

Verkorte titel

SELECT

Aandoening

Gallstones

Ondersteuning

Primaire sponsor: Team Westland, Reinier de Graaf Gasthuis

Overige ondersteuning: Reinier de Graaf Gasthuis, Team Westland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Number of stones that have passed spontaneously

Toelichting onderzoek

Achtergrond van het onderzoek

The clinical relevance of CBD sludge and/or small stones in patients with symptomatic cholecystolithiasis or choledocholithiasis is subject of debate. Although small gallbladder and/or common bile duct stones seem to be associated with an increased risk of biliary pancreatitis, other studies have shown a significant likelihood of spontaneous passage into the bowel without any complications. Smaller stones seem to have a significant chance to pass into the bowel spontaneously. Besides the size of the stone also the time between diagnosis and treatment is described as a factor that might influence the spontaneous passage of gallstones from the CBD.

EUS and ERCP are often planned in the same session, in order to be time efficient. If part of the stones pass spontaneously, this time efficient strategy leads to unnecessarily treated patients. The objectives of this study are 1. to investigate the rate of spontaneous (without ERCP) passing gallstones in patients with CBD stones ($\geq 3\text{mm}$). 2. to investigate if the rate of spontaneous passing stones is influenced by the time between EUS and ERCP and the size of the diagnosed stone(s). 3. To investigate the clinical relevance of sludge and microlithiasis ($< 3\text{mm}$) in the CBD during a watchful wait strategy.

Doel van het onderzoek

About 15% of the patients with gallstones detected by EUS will pass the stones spontaneously into the bowel. This means that in these 15% unnecessary ERCP can be avoided.

Onderzoeksopzet

Not applicable

Onderzoeksproduct en/of interventie

Extra second EUS, just before the potentially planned ERCP.

Contactpersonen

Publiek

Reinier de Graaf Gasthuis
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Wetenschappelijk

Reinier de Graaf Gasthuis
Hannah Schutz

06-42533020

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patient age $\geq$ 18 years old.
- Written informed consent.
- Diagnosed with gallstones or sludge based on positive findings at EUS or transabdominal ultrasound.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Clinical ascending cholangitis
- Severe colic pain
- Any other indication that made the physician decide to perform an ERCP directly at presentation (or at least before the scheduled ERCP).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status: Werving nog niet gestart

(Verwachte) startdatum: 02-08-2020

Aantal proefpersonen: 57

Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum: 03-07-2020

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

NTR-new

Ander register

ID

NL8751

METC Erasmus MC : MEC-2020-0215

Resultaten