

# Selecting Expected choledocho-Lithiasis patients for Endoscopic Therapy

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON21673

### Source

NTR

### Brief title

SELECT

### Health condition

Gallstones

## Sponsors and support

**Primary sponsor:** Team Westland, Reinier de Graaf Gasthuis

**Source(s) of monetary or material Support:** Reinier de Graaf Gasthuis, Team Westland

## Intervention

## Outcome measures

### Primary outcome

Number of stones that have passed spontaneously

### Secondary outcome

Time between first and second EUS in patients with stones that have passed spontaneously

## Study description

### Background summary

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.

### Study objective

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.

### Study design

Not applicable

### Intervention

Extra second EUS, just before the potentially planned ERCP.

## Contacts

### Public

Reinier de Graaf Gasthuis  
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### Scientific

Reinier de Graaf Gasthuis

## Eligibility criteria

### Inclusion criteria

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

### Exclusion criteria

- 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).

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	02-08-2020
Enrollment:	57

Type: Anticipated

## IPD sharing statement

Plan to share IPD: No

## Ethics review

Positive opinion

Date: 03-07-2020

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	NL8751
Other	METC Erasmus MC : MEC-2020-0215

## Study results