# Endoscopic sphincterotomy before fully covered self-expandable metal stent placement for malignant extrahepatic biliary obstruction to prevent pancreatitis: a randomised controlled trial

Published: 18-01-2016
Last updated: 15-05-2024

To investigate the role of endoscopic sphincterotomy prior to biliary fully covered SEMS (FCSEMS) placement in the prevention of post-ERCP pancreatitis.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Gastrointestinal inflammatory conditions |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON55849

**Source**
ToetsingOnline

**Brief title**
Sphinx

### Condition

- Gastrointestinal inflammatory conditions
- Gastrointestinal neoplasms malignant and unspecified

**Synonym**
Post-ERCP pancreatitis

**Research involving**

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Wij hebben een subsidieaanvraag ingediend bij COOK Medical en zijn in afwachting van een reactie.

## Intervention

**Keyword:** endoscopic sphincterotomy, extrahepatic cholestasis, post-ERCP pancreatitis, stents

## Outcome measures

### Primary outcome

Incidence of post-ERCP pancreatitis.

### Secondary outcome

- 30-day morbidity related to ERCP (with or without sphincterotomy)

- Technical success of stent placement

- Stent-related 30-day morbidity

- 30-day mortality

# Study description

### Background summary

Self-expandable metal stents (SEMSs) are increasingly being used to treat malignant common bile duct obstruction. This shift towards SEMS placement (and away from plastic stent placement) is accompanied by a change in the complication profile of biliary stent placement, with a sharp decrease in late occlusion and cholangitis, but a slight increase in the incidence of post-ERCP pancreatitis. It is hypothesised that endoscopic sphincterotomy before biliary SEMS placement may reduce the occurrence of post-ERCP pancreatitis by widening the orifice of the major duodenal papilla and reducing compression of the pancreatic sphincter. Data on whether or not to perform ES are conflicting. As a result, the European guideline leaves pre-stenting biliary sphincterotomy to the preference of the endoscopist.

### Study objective

To investigate the role of endoscopic sphincterotomy prior to biliary fully covered SEMS (FCSEMS) placement in the prevention of post-ERCP pancreatitis.

### Study design

A multicentre, open, randomised controlled trial.

### Intervention

Patients will be randomised to FCSEMS placement with or without prior endoscopic biliary sphincterotomy.

### Study burden and risks

All patients are consented for ERCP, and for the study, and informed about the complications associated with an ERCP: abdominal pain, bleeding, post-ERCP pancreatitis and perforation (consent for ERCP). The main risks of endoscopic sphincterotomy are haemorrhage (2.0%) and perforation (0.3%). In daily practice, whether or not the patient will be subjected to a sphincterotomy depends on the endoscopist*s preference. Therefore, the study does not introduce an additional risk for the participant.
The presumed benefit of an endoscopic sphincterotomy is a reduction in the post-ERCP pancreatitis rate after biliary SEMS placement, but sphincterotomy may be accompanied by an increased risk of bleeding and perforation. Therefore, a change in the distribution of complications could be anticipated.
The burden for patients participating in this trial is small, with only two short telephone calls seven and thirty days after the procedure to evaluate possible procedure-related complications.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

• Indication for fully covered self-expandable metal stent placement
• (Suspected) malignant biliary outflow obstruction
• Biliary stenosis located >= 2 cm distal from the hilum
• Age >= 18 years
• Written informed consent for the procedure and study participation

## Exclusion criteria

• Hilar biliary obstruction, defined as stenosis located within 2 cm of the hilum
• Biliary SEMS or more than 1 plastic endoprothesis in situ
• Precut sphincterotomy or standard sphincterotomy
• Prophylactic pancreatic duct stent, even when the PD-stent is subsequently removed
• Continued use of anticoagulants or antiplatelet drugs with the exception of low-dose aspirin (max. 100 mg/day)
• Known clotting disorder
• Patients unable to provide written consent for the study

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Prevention

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 03-05-2016 |
| Enrollment: | 511 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 18-01-2016 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 23-12-2016 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 16-10-2017 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 25-09-2018 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 08-10-2018 |
| Application type: | Amendment |

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| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 02-11-2018 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 28-01-2019 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 25-02-2019 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 30-04-2019 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 20-05-2020 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 06-08-2020 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

ID: 21209
Source: NTR

Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL54248.018.15 |
| OMON | NL-OMON21209 |