Endoscopic cutting of the constrictor (sphincter) muscle of the bile ducts before placement of a metal tube (stent) to lower the risk of an inflammation of the pancreas

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We hypothesise that endoscopic sphincterotomy before biliary fully covered self-expandable metal stent (FCSEMS) placement may reduce the occurrence of post-ERCP pancreatitis by widening the orifice of the major duodenal papilla and reducing...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms
Study type	Interventional

Summary

ID

NL-OMON21209

Source
NTR

Brief title
SPHINX

Condition

- Hepatobiliary neoplasms

Health condition

Malignant biliary obstruction Endoscopic biliary sphincterotomy Post-ERCP pancreatitis

Research involving
Human

Sponsors and support

Primary sponsor: Cook medical
Source(s) of monetary or material Support: Applied for a grant from Cook Medical, Ireland

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

Incidence of post-ERCP pancreatitis

Secondary outcome

- 30-days ERCP-related morbidity

- 30 days stent-related morbidity

- 30 days mortality

- Technical success of stent placement

Study description

Background summary

In this multicenter, open, randomised controlled trial we investigate the role of endoscopic sphincterotomy prior to biliary FCSEMS placement in the prevention of post-ERCP pancreatitis. Patients with extrahepatic malignant biliary obstruction requiring FCSEMS placement will be randomised between yes/no biliary sphincterotomy prior the FCSEMS placement. The primary endpoint is the incidence of post-ERCP pancreatitis.

Study objective

We hypothesise that endoscopic sphincterotomy before biliary fully covered self-expandable metal stent (FCSEMS) 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.

Study design

Primary and secondary endpoints will be evaluated at day 7 and day 30 after ERCP.

Intervention
ERCP with sphincterotomy and fully covered metal stent

Contacts

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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
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. 100mg/day)

- Known clotting disorder

- Patients unable to provide written consent for the study

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Historical
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-05-2016
Enrollment:	518
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO Date:	18-01-2016
Application type:	First submission
Review commission:	Stichting Beoordeling Ethiek Biomedisch Onderzoek Dr. Nassaulaan 10 9401 HK Assen 059 2405871 info@stbebo.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 55849
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5130
NTR-old	NTR5270
Other	MEC AMC : 2015_176
CCMO	NL54248.018.15
OMON	NL-OMON55849

Study results