EUS-guided choledochoduodenostomy (versus ERCP) for primary drainage of malignant distal biliary obstruction: a pilot study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23030

Source
Nationaal Trial Register

Brief title
SCORPION-pilot

Health condition

Adult patients with malignant distal biliary obstruction that require biliary decompression.

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Pending

Intervention

Outcome measures

Primary outcome

To establish the technical success of EUS-CD for the primary drainage of malignant distal

biliary obstruction. Technical success is defined as successful creation of a choledochoduodenostomy using a LAMS, which is directly confirmed by a cholangiogram.

Secondary outcome

- What is the clinical success rate of EUS-CD?
- What is the procedure time of EUS-CD?
- What is the adverse events rate of EUS-CD?
- What is the delayed time to treatment (surgery, chemo- or radiotherapy) due to adverse events after EUS-CD?
- What is the stent patency of EUS-CD?
- What is the need for reinterventions of EUS-CD?
- What is the overall survival time after EUS-CD?
- What are intraoperative findings and difficulties after EUS-CD?
- What are the costs involved with EUS-CD?

Study description

Background summary

Endoscopic retrograde cholangiopancreatography (ERCP) has been the primary approach to decompress the bile duct in patients with a malignant biliary obstruction. In spite of extensive experience with this technique in the Netherlands the technical success of ERCP in these patients is only 75%. Complications of ERCP such as post-procedural pancreatitis (3,5 - 10%), bleeding (0,3 - 9%), cholangitis (0,5 - 3%), cholecystitis (0,5 - 5,2%) and perforation (0,08-0,6%) are also not uncommon. Endoscopic ultrasound-guided choledochoduodenostomy (EUS-CD) obviates the need to reach the papilla and, in contrast to ERCP, is feasible in patients with duodenal obstruction. By bypassing the pancreas and the tumour EUS-CD does not lead to post-procedural pancreatitis. Three randomized controlled trials in international expert centres in North-America and Asia have compared EUS-CD versus ERCP which showed similar technical success, but lower adverse events and longer stent patency in EUS-BD. More data is needed to assess whether EUS-CD is indeed superior to ERCP as primary drainage strategy in patients with distal malignant biliary obstruction. In this pilot study the effectiveness and safety of EUS-CD will be evaluated in our tertiary referral center, and if satisfactory, a multicentre randomized controlled trial will be initiated.

Study objective

A 95% technical success rate is expected

Study design

Baseline: bilirubin levels
2 weeks after the procedure: consultation and bilirubin levels

4 weeks after the procedure: consultation and bilirubin levels
Every 3 months after the procedure: consultation and bilirubin levels

Patients will be followed up until pancreaticoduodenectomy or death.

Intervention

EUS-guided choledochoduodenostomy

Contacts

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Eligibility criteria

Inclusion criteria

- Radiographically (CT or EUS) distal malignant bile duct obstruction.
- Histology or cytology proven malignancy of the primary tumour or metastasis; onsite cytology evaluation after EUS guided fine-needle sampling that is highly suspected of a malignancy suffices.
- Indication for biliary drainage; in case of an resectable tumour this should be discussed during a clinical multidisciplinary meeting.
Written informed consent.

Exclusion criteria

- Age < 18 year.
- Surgically altered anatomy after previous gastric, periampullary or duodenal resection.
- Cancer extending into the antrum or proximal duodenum.
- Extensive liver metastases.

- WHO performance score of 4 (in bed 100% of time).
- Uncorrectable coagulopathy, defined by INR>1.5 or platelets < 50 x 109/L.
- Clinically relevant gastric-outlet obstruction.
- Unable to complete sign informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-09-2021
Enrollment:	21
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	28-09-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 51255
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9757
CCMO	NL77539.029.21
OMON	NL-OMON51255

Study results