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

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To establish the effectiveness and safety of EUS-CD as the primary drainage strategy in patients with malignant distal biliary obstruction.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Interventional

Summary

ID

NL-OMON51255

Source
ToetsingOnline

Brief title
SCORPION-pilot study

Condition

- Gastrointestinal stenosis and obstruction
- Bile duct disorders
- Hepatobiliary therapeutic procedures

Synonym
Biliary obstruction (malignant)

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Choledochoduodenostomy, Endosonography

Outcome measures

Primary outcome

The primary endpoint is technical success.

Secondary outcome

Secondary endpoint are clinical success, procedural time, adverse events, stent patency, need for reinterventions, technical outcome at pancreaticoduodenectomy (when applicable), and cost.

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 78%.[1] 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.[2] Endoscopic ultrasound-guided choledochoduodenostomy (EUS-CD) is a relatively new technique that allows the endoscopist to create a bypass between the bile duct and the duodenum by placing a lumen apposing metal stent (LAMS). 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.[3-5] 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

To establish the effectiveness and safety of EUS-CD as the primary drainage strategy in patients with malignant distal biliary obstruction.

Study design

Prospective, monocenter, single-arm, interventional, pilot study

Intervention

All patients will be treated with the investigational treatment (EUS-CD).

Study burden and risks

Participation in this therapeutic study offers patients with malignant biliary obstruction the opportunity to undergo EUS-CD as the primary drainage strategy. The burden and risk of EUS-CD are expected to be lower than those of the standard treatment (ERCP). The burden of follow-up within this study is limited and mainly concerns follow-up phone calls and laboratory tests 2 weeks, 1 month, and every 3 months after the procedure that evaluates whether stent related problems have occurred.

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

- Radiographically (CT, 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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-10-2021
Enrollment:	21
Type:	Actual

Ethics review

Approved WMO Date:	22-09-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-10-2021
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: 23030
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL77539.029.21
OMON	NL-OMON23030