EUS-guided choledochoduodenostomy for primary drainage of malignant distal biliary obstruction: a pilot study using FCSEMS through LAMS

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To reduce stent dysfunction after EUS-CDS by placing a FCSEMS through the LAMS, while maintaining effectiveness and safety of EUS-CDS as primary drainage strategy in patients with malignant distal biliary obstruction.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON53481

Source
ToetsingOnline

Brief title
SCORPION-II-pilot study

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
Distal malignant biliary obstructie

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Biliary obstruction, Choledochoduodenostomy, Endoscopic ultrasound

Outcome measures

Primary outcome

The primary endpoint is stent dysfunction.

Secondary outcome

Secondary endpoints include technical success, clinical success, procedural time, other adverse events, time to stent dysfunction, need for re-interventions. Patients will be followed up for at least six months, until pancreaticoduodenectomy, or death

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. However, complications of ERCP such as post-procedural pancreatitis (3.5 - 19%), bleeding (0.3 - 9%), cholangitis (0.5 - 11%), cholecystitis (0.5 - 5.2%) and perforation (0.08-2%) are not uncommon.(1, 2) Endoscopic ultrasound-guided choledochoduodenostomy (EUS-CDS) 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). By bypassing the pancreas EUS-CDS does not lead to post-procedural pancreatitis. In previous performed pilot study the effectiveness and safety of EUS-CDS has been shown in 21 patients. The high technical success rate (91%) and lack of pancreatitis in this study were satisfying. Unfortunately, stent dysfunction due to either food impaction or presumed obstruction of the stent by the contralateral bile duct wall occurred more often than expected (30-40%). Presumably the short length and perpendicular angle of the stent to the bile duct contribute to the risk of stent dysfunction. Therefore, a second pilot study will investigate whether placement of a fully covered self-expandable metal stent (FCSEMS) through the LAMS, which will create a barrier between bile

ducts and duodenum as well as optimize the angle of the stent, will decrease the risk of stent dysfunction while maintaining high technical success and low adverse event rates.

Study objective

To reduce stent dysfunction after EUS-CDS by placing a FCSEMS through the LAMS, while maintaining effectiveness and safety of EUS-CDS as 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-CDS).

Study burden and risks

Participation in this therapeutic study offers patients with malignant biliary obstruction the opportunity to undergo EUS-CDS as the primary drainage strategy. The burden and risk of EUS-CDS are expected to be lower than those of the standard treatment (ERCP). Follow-up is according to standard of care, telephonic consult and laboratory tests 2 weeks, 1 month, and every 3 months after the procedure.

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 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 a resectable tumour this should be discussed during a clinical multidisciplinary meeting

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 10^9/L*
- Clinically relevant gastric-outlet obstruction
- Unable to complete sign informed consent

* Inclusion is allowed after corrective treatment measures are taken, according to local protocol and treating physician.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-12-2022
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Hot AXIOS (LAMS) and Wallflex (FCSEMS)
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	20-10-2022
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL81840.029.22