Endoscopic drainage of presumed resectable perihilar cholangiocarcinoma using a novel design short fully covered self-expanding metal stent with retrieval string (CHORDA)

Published: 26-03-2021
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To explore feasibility and efficacy of endoscopic unilateral drainage of patients with presumed perihilar cholangiocarcinoma eligible for major liver resection using a novel fully covered metal stent with a retrieval string.

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

Summary

ID

NL-OMON50887

Source
ToetsingOnline

Brief title
CHORDA-pilot

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
cancer of the bile ducts, Cholangiocarcinoma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: FCSEMS, Kaffes stent, Perihilar cholangiocarcinoma, Pre-operative biliary drainage

Outcome measures

Primary outcome

Primary outcome: number of severe drainage related complications between inclusion and exploratory laparotomy. In patients who will not undergo exploratory laparotomy, the number of drainage-related complications will be measured until 7 days after the decision to cancel exploratory laparotomy or 90 days after inclusion, whichever comes first.

Secondary outcome

Secondary outcome will include technical and therapeutic success of biliary drainage, individual components of primary endpoints and quality of life.

Study description

Background summary

Pre-operative biliary drainage is advised to treat obstructive jaundice and optimize the clinical condition of patients with presumed resectable perihilar cholangiocarcinoma who are expected to be eligible to major liver resection. However, stent related complications such as cholangitis (37%) and stent dysfunction (19%) occur frequently. Creating the need for numerous re-inventions, re-admissions, delay of diagnostic work-up and surgery. Biliary drainage could be optimized by the use of a novel design short fully covered self-expanding metal stent (FCSEMS) with a retrieval string, which makes removal possible although the stent does not reach into the duodenum.

Study objective

To explore feasibility and efficacy of endoscopic unilateral drainage of patients with presumed perihilar cholangiocarcinoma eligible for major liver resection using a novel fully covered metal stent with a retrieval string.

Study design

Prospective cohort pilot study.

Intervention

Unilateral endoscopic drainage of the future liver remnant using a removable FCSEMS (length 4 cm; diameter 8 mm).

Study burden and risks

The relatively large diameter of the stent presumably leads to less stent occlusion and reduction in re-interventions. Furthermore, because the stent does not bridge the papilla, risk of ascending cholangitis might be lower. Besides the use of a different stent patients receive standard of care. Additionally, patients are requested to fill out questionnaires concerning their quality of life at baseline, 7 days, 28 days and 90 days after inclusion

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with presumed perihilar cholangiocarcinoma that are judged eligible for major liver resection and require endoscopic biliary drainage of the future liver remnant.

Exclusion criteria

- Incompletely recovered from any side effects of previous biliary drainage procedures
- Any contra-indication for major liver surgery
- Technical contra-indications for endobiliary drainage
- Requirement of multiple stents for adequate drainage of the future liver remnant

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	12-04-2021
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Niti-S Kaffes Biliary Stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	26-03-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-05-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-05-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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	NL76466.018.21