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

No registrations found.

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

Summary

ID

NL-OMON22954

Source
Nationaal Trial Register

Brief title
CHORDA-pilot

Health condition

(Potentially) resectable perihilar cholanhiocarcinoma

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Number of severe drainage related complications between inclusion and exploratory laparotomy. Severe complications are defined as any complication leading to additional invasive interventions, (extended) hospitalization, or death. 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

- The separate incidence of preoperative cholangitis.
- The number of drainage procedures required to achieve technical success.
- The proportion of patients with therapeutic success.
- The total number of drainage procedures that involved (attempted) stent (re-)placement.
- Interval bilirubin decrease at 7 days and 14 days after biliary drainage relative to the bilirubin level at inclusion.
- The number of patients with rescheduled or cancelled laparotomy due to severe drainage-related complications.
- Quality of life.
- Postoperative morbidity and mortality, among patients who underwent combined extrahepatic bile duct and liver resection.

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 for 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. The feasibility and efficacy of the use of this stent in patients with presumed perihilar cholangiocarcinoma eligible for major liver resection will be studied in this prospective cohort pilot study of 20 patients.

Study objective

It is hypothesized that endoscopic 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. The relatively large diameter (6, 8, or 10mm instead of 2.3 - 3.3mm diameter of plastic stents), presumably leads to less stent occlusion and reduction in re- interventions. Secondly, because the stent does not bridge the papilla, risk of ascending cholangitis might be lower.

Study design

- Baseline: laboratory tests, questionnaires
- 7 days: laboratory tests, questionnaires, abdominal ultrasound
- 14 days: laboratory tests
- 28 days: questionnaires
- 90 days: questionnaires
- Every 3 months (as long as Kaffes biliary stent is in situ): consultation and stent exchange

*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.

Intervention

Unilateral endoscopic drainage of the future liver remnant using a removable FCSEMS (Niti-S Kaffes Biliary stent, TaeWoong Medical Co., Ltd., Seoul, Korea).

Contacts

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Eligibility criteria

Inclusion criteria

- 18 years or older.
- Capable of providing written and oral informed consent.
- Presumed perihilar cholangiocarcinoma.
- Biliary obstruction in the future liver remnant.
- Drainage naïve patients: total bilirubin >50 umol/L
- Patients with previous endobiliary drainage procedures: persistently rising total bilirubin

>50 umol/L (i.e. no stent placed or insufficient draining stent) or persistent biliary dilatation in the future liver remnant on imaging (i.e. previous stent placed in contralateral side of the liver).

Exclusion criteria

- Incompletely recovered from any side effects of previous biliary drainage procedures. Patients are required to be off antibiotic treatment for at least 5 days.
- Any contra-indication for major liver surgery (e.g. ECOG/WHO score 3 or higher).
- Technical contra-indications for endobiliary drainage (e.g. previous gastrojejunostomy).
- Refusal to provide informed consent.
- Requirement of multiple stents for adequate drainage of the future liver remnant (e.g. involvement of segmental bile ducts).
- In case it is not feasible to prevent blockage of one or more large segmental branches.

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):	01-04-2021
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	09-04-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 56262
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9394
CCMO	NL76477.042.21
OMON	NL-OMON56262

Study results