Endoscopic drainage of presumed resectable perihilar cholangiocarcinoma using a intrahepatic plastic stent with retrieval string; a pilot study (CHORDA-II-pilot)

Published: 15-02-2023
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To explore feasibility and efficacy of endoscopic drainage of patients with presumed perihilar cholangiocarcinoma eligible for major liver resection using a plastic 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-OMON53365

Source
ToetsingOnline

Brief title
CHORDA-II-pilot

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
bile duct cancer, Cholangiocarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Intrahepatic plastic stent with retrieval string, 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 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 potential surgery. Biliary drainage could be optimized by the use of a novel design short fully covered self-expanding metal stent (FCSEMS) which is currently examined in the CHORDA-pilot study. However, FCSEMS placement is not feasible in an considerable number of cases, in these patients the use of a plastic stent with

a retrieval string could be beneficial over standard plastic stent placement, which makes removal possible although the stent does not reach into the duodenum.

Study objective

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

Study design

Prospective cohort pilot study.

Intervention

Endoscopic drainage of the future liver remnant using a plastic biliary stent with retrieval string (diameter 7 or 10Fr).

Study burden and risks

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
Amsterdam UMC

Boelelaan 1118
Amsterdam 1081 HV
NL
Scientific
Amsterdam UMC

Boelelaan 1118
Amsterdam 1081 HV
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

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2023
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Intrahepatic plastic biliary stent with retrieval string
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	15-02-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-07-2024
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

No registrations found.

In other registers

Register	ID
CCMO	NL83570.018.22