Uncovered self-expandable metallic stent for preoperative biliary drainage in patients with resectable perihilar cholangiocarcinoma

No registrations found.

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

Summary

ID

NL-OMON21193

Source
NTR

Brief title
UMBRELLA

Health condition

Perihilar cholangiocarcinoma

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The primary objective of this study is to assess the feasibility of ucSEMS placement in

patients with resectable pCCA defined as:
· At least 70% of patients with technical successful ucSEMS placement, that is:
o Placed in the segment(s) to be drained as determined by the multidisciplinary meeting, with a preferred margin of at least 1 cm proximally and distally across the stenosis
o Bilirubin decrease of at least 20% after 7 days
o No need for additional biliary drainage intervention (ERCP and/or PTCD)

Secondary outcome

The secondary objective of this study is to assess the safety of ucSEMS placement in patients with resectable pCCA by using the following parameters:
· A maximum of 50% of patients with severe post-procedural complications. Complications are defined and subcategorized as:
o Endoscopic (ucSEMS placement)
■ Moderate or severe post-ERCP pancreatitis: defined as (i) new or worsened abdominal pain; (ii) new or prolonged hospitalization for at least two days; and (iii) serum amylase or lipase > threefold upper limit of normal, measured >24h after the procedure, according to the Atlanta Revised Criteria (17)
■ Cholangitis, which was defined as both fever (i.e. body temperature >38.5°C) and leucocytosis (i.e. ≥10 *109/L) without clinical or radiological evidence of acute cholecystitis, requiring prolonged antibiotics and re-intervention
■ Radiologic evidence of cholecystitis, elevation in temperature more than 38.5°C and Leukocytes ≥10*109/L, and requirement of percutaneous drainage or emergency cholecystectomy.
■ Major Bleeding: defined as a hemoglobin drop of >3g/dl requiring any re-intervention (endoscopic, angiographic, surgical)
■ Perforation: defined as evidence of air or luminal contents outside the gastro-intestinal tract together with clinical symptoms, requiring percutaneous drainage or surgery
o Stent-related (after placement)
■ Stent dislocation
■ Stent occlusion
■ Bile leakage requiring re-intervention (percutaneous, endoscopic, or surgical)
■ Intra-abdominal abscess requiring drainage
· Technical success of stent removal, defined as successful removal during surgery by the surgeon on a range from 0 – 10 and duration of removal
· Accuracy of extent of the tumor on CT, MRCP and ERCP in comparison with pathological resection specimens.

Study description

Background summary

Biliary drainage in patients with perihilar cholangiocarcinoma is often performed by endoscopic placement of plastic or metal stents. Preoperatively this is mostly limited to

plastic stents, but these are known to have limited patency time. The uncovered self-expanding metal stent allows for more rapid biliary decompression and has a reduced occlusion rate when compared to plastic stents. However, there is limited published evidence about the application of ucSEMS in the preoperative setting.

Study objective

Metal stents are safe and a feasible for preoperative biliary draqinage for resectable perihilar cholangiocarcinoma

Study design

Imaging, ERCP (Intervention), surgery (if performed)

Intervention

ucSEMS placement by ERCP

Contacts

Public
Erasmus University MC
David de Jong

+31 6 1783 1114
Scientific
Erasmus University MC
David de Jong

+31 6 1783 1114

Eligibility criteria

Inclusion criteria

• High suspicion of resectable pCCA on imaging (as determined by the multidisciplinary hepatobiliary team, with or without histopathological confirmation) And
• Preoperative endoscopic drainage is indicated (as determined by the multidisciplinary hepatobiliary team) And
• Written informed consent according to ICH/GCP, and national/local regulations. And

• Age > 18 years

Exclusion criteria

• Patients who underwent previous drainage procedures by endoscopy with plastic stent placement or percutaneously with an (internalized) biliary catheter; And
• Bismuth type I pCCA (as determined by the multidisciplinary hepatobiliary team); And
• Prior diagnosis of Primary Sclerosing Cholangitis (PSC)

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):	05-07-2021
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	05-07-2021
Application type:	First submission

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
NTR-new	NL9600
Other	METC EMC : MEC-2021-0420

Study results