Primary percutaneous stenting of the bile ducts in patients with resectable perihilar cholangiocarcinoma - a pilot study

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To analyse complications due to primary percutaneous stenting in patients with resectable pCCA.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bile duct disorders
Study type	Interventional

Summary

ID

NL-OMON56845

Source
ToetsingOnline

Brief title
TESLA 2 pilot

Condition

- Bile duct disorders

Synonym
Bile duct cancer, malignant hilar biliary obstruction

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: biliary drainage, metal stent, perihilar cholangiocarcinoma, primary percutaneous stenting

Outcome measures

Primary outcome

Major complications within 90 days after inclusion.

Secondary outcome

Severe drainage-related complications within 90 days after inclusion; absolute and relative (%) bilirubin decrease after 14 days (+/-4 days); proportion of patients with technical success of stent placement at initial drainage procedure; proportion of patients with successful drainage at initial drainage procedure; number of reinterventions and hospital admission days; proportion of patients who underwent surgical exploration and who underwent curative-intent surgical resection; proportion of uncomplicated stent removal from the future liver remnant during surgery; overall survival (OS); and cost-effectiveness.

Study description

Background summary

Perihilar cholangiocarcinoma (pCCA) is a rare tumour originating in the bile ducts at the liver hilum. These patients present with jaundice due to biliary obstruction and 25% are eligible for a curative-intent major liver resection. Preoperative biliary drainage is required to resolve the biliary obstruction, because without drainage the liver cannot regenerate after a major liver resection, resulting in postoperative liver failure and mortality.

Dutch and international guidelines recommend an endoscopic approach for biliary drainage. An endoscopic stent in the bile duct crosses not only the tumor, but also the ampulla, which is a sphincter that keeps enteral contents out of the biliary tree. A stent that crosses the ampulla causes bacterial colonization of

the previously sterile intrahepatic bile ducts. Recurring cholangitis often develops, requiring multiple reinterventions, hospital admissions, clinical deterioration, and even death in many patients. In a Dutch multicenter RCT (the DRAINAGE trial), this approach was compared with percutaneous biliary drainage. Unfortunately, percutaneous drainage was not better, probably because the percutaneous drain also crosses the ampulla.

The potential solution to this clinical problem is primary percutaneous stenting. Fenestrated self-expandable metal stents (SEMS) are used that do not cross the ampulla, avoiding bacterial colonization of the bile ducts. Moreover, no external percutaneous biliary drain is used, avoiding bacterial colonization of the bile ducts with skin bacteria. In the TESLA trial (MEC-2019-0789), we have used this approach in 35 patients who were ineligible for resection. Compared to a historical cohort with endoscopic drainage, we found a substantial decrease in 90-day mortality from 35% to 7% and a cost saving of about 8,000 euro per patient in the first 90-days. Primary percutaneous stenting has never been investigated in resectable pCCA.

Study objective

To analyse complications due to primary percutaneous stenting in patients with resectable pCCA.

Study design

We aim to perform a proof-of-concept pilot study at Erasmus MC, including 12 patients. The expected inclusion period is less than 2 years, based on historical annual volume and accrual proportion of eligible patients in the TESLA trial for unresectable pCCA.

Intervention

Primary percutaneous stenting with fenestrated self-expandable metal stents (SEMS) without crossing the ampulla and without leaving an external drain after stent placement.

Study burden and risks

Primary percutaneous stenting is an alternative approach to the standard of care, which is endoscopic biliary drainage. Complications due to the transhepatic biliary drainage, i.e. bleeding, infection and bile leakage are uncommon (<5%).
We hypothesize that PPS in patients with resectable pCCA minimizes post-drainage cholangitis and mortality, requires fewer reinterventions, and increases the rate of patients receiving a curative-intent resection.
In this study, patients will undergo an invasive procedure with hospital

discharge the next day. This corresponds to the standard of care. Follow-up is planned after 14 days (+/- 4 days), according to standard of care.

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

• Written informed consent must be given according to ICH/GCP, and national/local regulations.
• Resectable pCCA on imaging with histopathological confirmation or high clinical suspicion (as determined by the multidisciplinary hepatobiliary team).
• Hyperbilirubinemia (a combination of a total bilirubin level >50 mmol/l.
• Age above 18 years

Exclusion criteria

• Fluctuation or spontaneous decrease of a total bilirubin level before start of any treatment suggesting potential benign origin.
• Patients who underwent previous drainage procedures endoscopically or percutaneously with an internalized biliary catheter.
• Clinical signs of cholangitis. Cholangitis was defined as the presence of both fever (i.e. body temperature >38.5°C) combined with leucocytosis (i.e. >=10 *109/L) without clinical or radiological evidence of acute cholecystitis
• Uncorrectable coagulation disorder.
• Uncorrectable contrast allergy.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-11-2024
Enrollment:	12
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	28-06-2024
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL82681.078.24
Other	volgt