Endobiliary radiofrequency ablation for malignant biliary obstruction due to perihilar cholangiocarcinoma: a randomized controlled trial

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The aim is to evaluate whether the use of eRFA prior to stenting prolongs stent patency in patients with biliary obstruction due to inoperable perihilar cholangocarcinoma.

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

Summary

ID

NL-OMON52313

Source
ToetsingOnline

Brief title
RACCOON

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: Cholangiocarcinoma, Malignant biliary obstruction, Radiofrequency ablation, Stent patency

Outcome measures

Primary outcome

The primary endpoint is the time to biliary obstruction.

Secondary outcome

Secondary endpoints include technical and functional success, the effect on

quality of life, overall survival, adverse events, number of re-interventions,

time to re-interventions, need for external drains, and evaluation of the

effect of repeated eRFA on stent patency.

Study description

Background summary

At time of diagnosis, only about 15-20% of the patients with cholangiocarcinoma qualify for curative resection. Consequently, the majority of patients need optimal palliative care. Due to tumour growth in the bile ducts almost all patients with perihilar cholangiocarcinoma develop bile duct obstruction in the course of their disease. Palliative treatment consists of placement of biliary stents to relieve this obstruction in combination with systemic therapy. However, stent patency is known to be short due to ingrowth of the tumour. This leads to recurrent cholangitis, sepsis, re-interventions and admissions, delay or cancellation of chemotherapy, permanent external drainage catheters, and, if adequate drainage cannot be achieved, death. The use of endobiliary radiofrequency ablation (eRFA) has been described as a promising adjuvant therapy to prolong stent patency and subsequent survival and quality of life.

Study objective

The aim is to evaluate whether the use of eRFA prior to stenting prolongs stent patency in patients with biliary obstruction due to inoperable perihilar cholangocarcinoma.

Study design

A multicentre, parallel group, open label, randomized controlled trial.

Intervention

eRFA prior to placement of an uncovered self-expanding metal stent (or plastic stent in case not feasible) compared with stent placement only.

Study burden and risks

It is hypothesized that eRFA leads to increased stent patency, less re-interventions, less (permanent) external drains, and consequently increased quality of life and survival. Adverse events (2-6%) have been reported after eRFA, however according to meta-analysis only temporary abdominal discomfort (31 vs 20%) seems to occur significantly more often in patients who underwent eRFA prior to stenting compared with stent placement only. Patients are requested to fill out questionnaires concerning their quality of life at baseline, 1 month, and every 3 months after intervention. Conform standard of care a telephonic or consult at the outpatient clinic in combination with laboratory tests will be performed at baseline, and 2 weeks, 1 month and every 3 months after intervention.

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

- 18 years or older.
- Capable of providing written and oral informed consent.
- Histological or cytological proof of perihilar cholangiocarcinoma (adenocarcinoma).
- Perihilar biliary obstruction with indication for drainage with uSEMS.*
- Advanced (no candidate for surgical resection) due to metastases, vascular or lymph node (N2). involvement on imaging or during staging laparoscopy according to multidisciplinary team (MDT).

*Only patients with pCCA are eligible however in case of reasonable doubt between intrahepatic CCA with a perihilar biliary obstruction or massforming pCCA, patients can be included.

Exclusion criteria

- Patients who potentially qualify for curative resection of pCCA.
- pCCA eligible for liver transplantation.
- Life-expectancy less than 3 months.
- ERCP and PTC technically not feasible.
- Uncontrolled coagulopathy (PTT >1,5x prolonged or thrombocytes below 40*10E9/L).
- Ongoing cholangitis or liver abscess. Patients are required to be off antibiotic treatment for cholangitis and/or liver abscess at least 7 days.
- Any condition that is unstable or that could jeopardize the safety of the subject and their compliance in the study.
- Patients who are pregnant or breastfeeding.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-10-2022
Enrollment:	73
Type:	Actual

Medical products/devices used

Generic name:	Endobiliary radiofrequency ablation (eRFA)
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	20-09-2022
Application type:	First submission
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	NL76591.029.22