Endobiliairy radiofrequency ablation for malignant biliairy obstruction, RACCOON-pilot

No registrations found.

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

Summary

ID

NL-OMON27848

Source
Nationaal Trial Register

Brief title
RACCOON-pilot

Health condition

Parihilair cholangiocarcinoma

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

The primary aim of the proposed pilot study is to evaluate whether eRFA is feasible, safe in patients with unresectable perihilar cholangiocarcinoma.

Secondary outcome

Recurrence of biliary obstruction, quality of life

Study description

Background summary

It is hypothesized that eRFA leads to increased stent patency, fewer re-interventions, fewer (permanent) external drains, and consequently increased quality of life. Currently eRFA for CCA has only been investigated in retrospective and small prospective pilot-studies. The primairy aim of the proposed pilot study is to evaluate whether eRFA is feasible and safe in patients with unresectable perihilar cholangiocarcinoma .

Study objective

It is hypothesized that eRFA leads to increased stent patency, fewer re-interventions, fewer (permanent) external drains, and consequently increased quality of life.

Study design

o Baseline: consultation + questionnaire + laboratory test
o 1 day after eRFA: consultation
o 2 weeks after eRFA: consultation + laboratory test
o 1 month and every 3 months after eRFA: consultation + questionnaire + laboratory test

Intervention

Endobiliary RFA

Contacts

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Eligibility criteria

Inclusion criteria

- 18 years or older.
- Capable of providing written and oral informed consent.
- Histological or cytological proof of perihilar CCA (adenocarcinoma)*
- Biliary obstruction with indication for drainage (symptomatic (itch or cholangitis) or necessary for systemic therapy).
- 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).

Exclusion criteria

- Resectable CCA.
- Intrahepatic or distal CCA, or gallbladder cancer.
- CCA eligible for liver transplantation.
- Life-expectancy less than 3 months.
- ERCP and PTD technically not feasible.
- Uncontrolled coagulopathy (PTT >1,5x prolonged or thrombocytes below 40 10E9/L).
- Carcinoma other than adenocarcinoma.
- Implantable pacemaker and implantable cardioverter/ defibrillator

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):	27-12-2020
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	27-12-2020
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	NL9144
Other	METC AMC : METC 2020_217

Study results