Circulating tumor DNA as biomarker for perihilar cholangiocarcinoma

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27478

Source
NTR

Brief title
TUPAC

Health condition

Perihilar cholangiocarcinoma/ Perihilair cholangiocarcinoom

Klatskin-tumor

Biomarker

Circulating tumor DNA /Circulerend tumor DNA (ctDNA)

Sponsors and support

Primary sponsor: AMC
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

The aim of this study is to investigate if ctDNA is detectable in the blood of patients with pathologically proven PHC.

Secondary outcome

We will perform mutation analyses on PHC samples to contribute to the literature on mutational profiles of PHC paving the way for implementation in clinical use.

Study description

Background summary

In suspected perihilar cholangiocarcinoma, the current diagnostic options are inadequate. Furthermore, a reliable biomarker that can be used for followup desirable. Circulating tumor DNA is promising in this regard.

The aim of this project is the detection and analysis of ctDNA in perihilar cholangiocarcinoma patients. A condition for the applicability of ctDNA as a biomarker is that the mutation profiles found in ctDNA and the tumor tissue are identical. For this reason, both tumor tissue and ctDNA will be sequenced.

Study objective

We expect to demonstrate that ctDNA can be reliably detected in patients with perihilar cholangiocarcinoma.

Study design

We hope to have collected the 20 patient samples before May 2017.

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

-Patients older than 18 years.

-Undergoing explorative laparotomy, diagnostic laparoscopy or percutaneous biopsy.

-Able to understand the information given and provide written informed consent.

Exclusion criteria

-Patients 18 years or younger.

-Unfit for laparotomy/ diagnostic laparoscopy/ biopsies or blood analyses in palliative chemotherapy studies.

-HIV/AIDS/hepatitis C in medical history.

-Not able to give informed consent (language, intellectual capacities, etc.).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-09-2016
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	31-08-2016
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	NL5793
NTR-old	NTR6068
Other	: Protocol ID: NL58159.018.16

Study results