Circulating tumor DNA as a biomarker in perihilar cholangiocarcinoma: a feasibility study

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In this study we hope to demonstrate the presence ofthat ctDNA can be reliably detected in patients with perihilar cholangiocarcinoma.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON43203

Source
ToetsingOnline

Brief title
circulating tumor DNA in perihilar cholangiocarcinoma

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary neoplasms malignant and unspecified

Synonym
biliary tract cancer, perihilar cholangiocarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Biomarker, ctDNA, Perihilar Cholangiocarcinoma

Outcome measures

Primary outcome

-To determine if ctDNA is presentcan be reliably detected in patients with PHC.

-If ctDNA is presentdetected, we will assess if the mutational profile of the

tumor matches the profile of the ctDNA

Secondary outcome

-To perform a hotspot mutation analysis in patients with pathologically proven

PHC

Study description

Background summary

Diagnosis of perihilar cholangiocarcinoma (PHC) is challenging due to low sensitivity and specificity of current diagnostic tests. 15% of Of all patients with suspected PHC who undergo surgical resection, 15% have a benign inflammatory disease at final histopathological diagnosis. Morbidity and mortality after liver resection for perihilar lesions is high; 8-15% mortality and 40-70% morbidity. Even for patients with pathologically proven PHC for whom surgery is the only curative option, this is a considerable risk. Ideally, patients with benign disease should therefore not be subjected to surgery. There is an urgent need for a diagnostic tool that is safe and reliably discriminates between malignant and benign biliary tract disease. Patient*s blood might be sufficient to provide us with information about the nature of the disease: a so called *liquid biopsy*. For more than 14 different tumor types, the presence of cell free circulating tumor DNA (ctDNA) in blood has been described. The presence of known cancer-causing mutations can distinguish tumor derived ctDNA from normal DNA. ctDNA has the potential to alter the management of cancer care, offering a non-invasive method for adequate diagnosis, identification of disease recurrence, and monitoring of therapy. The presence of ctDNA in cholangiocarcinoma patients has not been reported before, but has the potential to be an extremely useful and specific biomarker.

Study objective

In this study we hope to demonstrate the presence ofthat ctDNA can be reliably detected in patients with perihilar cholangiocarcinoma.

Study design

Observational prospective feasibility study

Study burden and risks

Risks associated with participation are negligible. For the participating patients, only 3 4 additional tubes of blood will be drawn subsequently to the routine preoperative blood tests. The findings of the mutation analyses will not be shared with the patients

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

-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

-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 invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-09-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	11-08-2016
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	NL58159.018.16