*The prognostic and predictive value of Organoids from vena porta-derived Single CTCs in patients with primary ColorectAl canceR for development of liver metastases a feasibility study' (OSCAR)

Published: 19-01-2018
Last updated: 12-04-2024

The main objective is to assess the feasibility of CTC organoid culture as a diagnostic and/or prognostic tool in patients with metastatic disease.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON48875

Source
ToetsingOnline

Brief title
OSCAR Trial

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Bowel Cancer, Colon Cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Circulating Tumor Cells, Colorectal Cancer, Organoids

Outcome measures

Primary outcome

The main study parameter is the number of patients from which viable Organoids can be cultured from CTCs. On the basis of this number prognostic follow up studies can be designed. With a success rate of 70% the study will be proven feasible.

Secondary outcome

Not applicable

Study description

Background summary

Mortality from colorectal cancer (CRC) is frequently due to the development of liver metastases. Clinicopathological features have limited power to identify patients at risk of relapse. The presence of circulating tumour cells (CTCs) may help to discriminate between patients with high and low risks of developing distant metastases. For CTCs to be used as a prognostic biomarker however, the sensitivity and specificity of detection need to be improved. Drawing blood from the portal vein, instead of using peripheral blood, increases the detection rate of CTCs. Assessment of regenerative potential of CTCs could provide information on the ability of CTCs to form liver metastases. By combining CTC purification from portal blood with organoid culture technologies, we aim to optimize the performance of CTCs as a prognostic tool.

Study objective

The main objective is to assess the feasibility of CTC organoid culture as a

diagnostic and/or prognostic tool in patients with metastatic disease.

Study design

A multi-centre feasibility study

Study burden and risks

No additional hospital visits are needed for this trial: blood samples will be collected during surgery. The risk of complications during portal venous blood collection is small since the collection of the sample will take place at the start of the procedure, the surgeon has a direct view of the portal vein during the rest of the procedure. Control of the puncture spot on the portal vein will be checked before the procedure is ended.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

1. Male or female aged *18 years;
2. Clinical diagnosis of colorectal carcinoma with synchronous liver metastases;
3. Scheduled resection of the primary tumour or resection of liver metastases with a liver-first approach;
4. Written informed consent.

Exclusion criteria

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Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-01-2020
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	19-01-2018
Application type:	First submission
Review commission:	METC NedMec

Approved WMO Date:	14-02-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	21-11-2019
Application type:	Amendment
Review commission:	METC NedMec

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	NL63625.041.17