AMC colorectal organoids biobank: a living biobank

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal conditions NEC
Study type	Observational non invasive

Summary

ID

NL-OMON45427

Source
ToetsingOnline

Brief title
Living CRC biobank

Condition

- Gastrointestinal conditions NEC
- Miscellaneous and site unspecified neoplasms benign

Synonym
colorectal cancer, Colorectal carcinoma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: chemosensitivity, colorectal cancer, Organoids

Outcome measures

Primary outcome

Primary research question is to evaluate the association and predictive value of sensitivity or resistance to chemotherapy of established primary human organoids and the response of patients to the same chemotherapy. In other words, what is the correlation between non-responsiveness of the organoids to a specific compound and recurrence of the disease in adjuvantly treated patients.

Secondary outcome

Secondary research questions include 1) association between non-responsiveness of the primary cultures and overall survival (OS) and disease free survival (DFS) 2) analysis of the success rate of establishment of colon organoids derived from patient material in a standardized clinical setting 3) We will further explore new intervention approaches that are effectively targeting the distinct subtypes, which will be carried forward into a spectrum of in vitro and in vivo models in order to develop these therapies for future use 4) In addition we will try to define the role of distinct mutations and the regulation of EMT mesenchymal features in colon cancer and to identify key players in this process in order to identify resistance mechanisms that play a role in this subgroup of cancers.

Study description

Background summary

Colon cancer is currently the leading cancer type in the Netherlands. When dealing with non-metastatic disease, the main problem is that it remains enigmatic which patients will develop a recurrence after successful resection of the primary cancer. This makes selection for adjuvant therapy an impossible yet essential objective. If anything, population-based CRC screening will intensify this dilemma as it will increase early stage diagnoses. On top of this current adjuvant therapy is curative only in part of the patients and therefore in urgent need of optimization. Using unbiased gene expression-based stratification, we and others have defined 4 consensus molecular subtypes with highly distinct biological and clinical traits, which suggests that colon cancer should no longer be considered and treated as a homogeneous disease.

Study objective

The aim of this proposal is to test this concept using organoid cultures and biobanked material of colon cancer patients and use these cultures to develop novel therapies in particular for the CMS4 subtype, which has mesenchymal features, a dismal prognosis and a reportedly poor response to therapy.

Study design

After informed consent, blood, tumor and normal tissue (FFPE and frozen) will be stored into a biobank. A portion of the CRC material will first be cultured before storing. Finally a drug screen will be performed on the collected material.

Study burden and risks

Since this study is a biobanking effort, there basically is no burden or risk associated with participation. Course of treatment will not be influenced by participation in this study. Only in case of colonoscopy patients may be asked for additional biopsies. This gives an almost neglectable potential additional risk of bleeds. Also patients may be asked for blood samples, preferentially when patients already undergo blood withdrawal.

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

1) (pre-stage) colorectal carcinoma 2) age of 18 or higher 3) scheduled for resection or colonoscopy 4) written informed consent for study participation

Exclusion criteria

None

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-03-2017
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	08-03-2017
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	NL59811.018.16