Tumor organoids: feasibility to predict sensitivity to treatment in cancer patients (TUMOROID trial)

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• Evaluate the potential of tumor organoid therapy response to predict treatment response in the patient • Design a standardized organoid screening test and propose a test threshold that ensures a high negative predictive value• Establish the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metastases
Study type	Observational invasive

Summary

ID

NL-OMON44690

Source
ToetsingOnline

Brief title
TUMOROID

Condition

- Metastases

Synonym
breast), colorectal, disseminated cancer (lung, Metastatic cancer

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: Zwaartekracht subsidie,KWF datamanagement subsidie & Pink Ribbon

Intervention

Keyword: Diagnostic test, Metastatic cancer, Predicting therapeutic response, Tumor organoids

Outcome measures

Primary outcome

• Area under the (partial) receiver operating characteristics (ROC) curve

• Optimal organoid screening test threshold and associated accuracy measures

(sensitivity, specificity, positive predictive value, negative

predictive value)

Secondary outcome

• Success rate of organoid culture from biopsies of colorectal, breast and lung

cancer

Study description

Background summary

Tumor organoids are three-dimensional cultures of cancer stem cells that can now be established on an individual patient basis. If tumor organoids are able to predict sensitivity to treatment, this can prevent unnecessary exposure to toxic agents and result in improved patient selection for treatment with targeted agents.

Study objective

• Evaluate the potential of tumor organoid therapy response to predict treatment response in the patient
• Design a standardized organoid screening test and propose a test threshold that ensures a high negative predictive value
• Establish the success rate of tumor organoid culture from biopsies of locally advanced disease or metastases of colorectal, breast and lung cancer in clinical practice

Study design

This is a multicenter observational cohort study evaluating the feasibility of using tumor organoids as a screening tool to predict treatment response to standard of care agents (i.e. chemotherapy, targeted agents and androgen depletion therapy) in patients with locally advanced (incurable) or metastatic colorectal, breast or lung cancer. In this trial patients will be asked to participate before they start treatment with any kind of standard of care agent specified in this protocol. If patients consent to participation they will undergo a biopsy procedure of the primary tumor or a metastatic lesion and a blood withdrawal before start of treatment. The biopsy specimen will be used to culture tumor organoids, which will subsequently be incubated with the same standard of care treatment as has been given to the patient. Afterwards, the in vitro response to treatment and the treatment response of the patient will be compared to establish if it is feasible to use tumor organoids as an instrument to predict response to treatment.
Patient treatment response will be recorded.

Study burden and risks

For all included patients, biopsies of the metastatic lesion or primary tumor will be performed in order to obtain material for organoid cultures. Ample experience exists with performing biopsies in patients with metastatic lesions and the procedure is considered to be safe. Alongside the tumor biopsies, three blood samples will be obtained to determine germline DNA and for biomarker research. Patients will be treated according to standard of care and clinical management of patients will be performed according to daily practice in participating institutions.

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 with locally advanced (incurable) or metastatic colorectal, breast or lung (non-small cell) cancer who will start treatment with one of the regimens specified in the protocol.
- Measurable/evaluable disease
- Safe histologic tumor biopsy possible
- WHO 0-2

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:	Recruitment stopped

Start date (anticipated):	01-10-2014
Enrollment:	665
Type:	Actual

Ethics review

Approved WMO Date:	09-07-2014
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	26-03-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-04-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	29-01-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	09-03-2017
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	NL49002.031.14