Immunogenicity of Tumor Organoids derived from colorectal, gastric, gynaecological and non-small cell lung cancer, a Feasibility Study

Published: 08-07-2014
Last updated: 21-04-2024

Establish the immunogenicity of tumor organoids in vitro

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON55942

Source
ToetsingOnline

Brief title
Immunogenicity of Tumor Organoids

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
colorectal cancer/bowel cancer, gastric cancer, non-small cell lung cancer/lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: Zwaartekracht subsidie

Intervention

Keyword: Colorectal cancer, Gastric cancer, Immunotherapy, Non-small cell lung cancer, Organoids

Outcome measures

Primary outcome

Reactivity of autologous T cells primed with tumor organoids

Secondary outcome

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Study description

Background summary

Tumor organoids are three dimensional cultures of cancer stem cells that can now be cultured on an individual patient basis. In this trial it will be established whether autologous tumor organoids are immunogenic. If this is the case it provides a rationale to intiate clinical intervention trials to evaluate whether tumor organoids can contribute to the development of patient-specific anti-tumor vaccines or the adoptive transfer of T cells primed in vitro with autologous tumor organoids.

Study objective

Establish the immunogenicity of tumor organoids in vitro

Study design

This is a protocol aimed at retrieving tumor tissue and blood from patients with colorectal, gastric, gynaecological and non-small cell lung cancer. Tumor tissue will be collected by the following means:
- During a biopsy procedure, that is done as part of a clinical study or as part of standard of care. One of the biopsy specimens retrieved at the biopsy procedure will be used for organoid culture.
- During a standard of care tumor resection (primary tumor or metastatic lesion). If possible, healthy tissue will also be retrieved and serve as a negative control
- For some patients tumor organoid cultures might have been previously derived using other protocols, for these patients only a blood withdrawal will be

performed.
The blood sample will be used to isolate peripheral blood mononuclear cells (PBMCs), which can subsequently be used to evaluate the in vitro immunogenic potential of autologous tumor organoids. A mandatory blood withdrawal of 80cc will be performed at baseline. An additional three 80cc blood withdrawals are allowed within the protocol and are optional, not mandatory. For the subsequent blood withdrawals, an optional serum-sample can be taken, to look for serological factors that may impact anti-tumor immunity. In this case, the amount of blood withdrawn for PBMCs can be diminished to a minimum of 40cc. Between each blood withdrawal, there will be a minimum interval of 1 month. When sufficient tumor material is present for organoid establishment, Tumor Infiltrating Lymphocytes (TILs) may be isolated from the remaining resection material. The reactivity of intratumoral immune cells can be determined using the matched organoids. Additionally, alternative immune cell subsets may be isolated from matched patient PBMCs to evaluate their specific reactivity. Exploration of potential biomarkers associated with immunogenicity may include, but is not limited to DNA/RNA sequencing or immunohistochemistry. Tumor digest (where available) can be used to evaluate tumor reactivity of autologous T cells towards digest and to compare this to the reactivity to tumor organoids.

Study burden and risks

In this study patients will undergo a blood withdrawal of 80cc. This blood withdrawal does not pose a risk to patients. Blood withdrawals are only performed if they are in accordance with the CMRC (Children*s Memorial Research Center) institutional review board maximum allowable total blood draw volumes. In some patients, additional blood withdrawal will be performed. This is limited to three blood withdrawals of 80cc and is optional for the patient. Tumor tissue for organoid culture will be retrieved during pre-planned procedures (tumor biopsies or resections) that are performed for other clinical studies or as part of standard of care. Patients will not benefit from participation, this trial will however provide important information that can result in future intervention trials that might benefit patients.

Contacts

Public
Nederlands Kanker Instituut

Plesmanlaan 121
Amsterdam 1066 CX
NL
Scientific
Nederlands Kanker Instituut

Plesmanlaan 121
Amsterdam 1066 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

i. Patients with colorectal, gastric, gynaecological or non-small cell lung cancer
ii. Undergoing a tumor biopsy or resection of the primary tumor/metastasis. With the exception of patients from whom tumor organoids cultures have been previously derived
iii. Eligible for blood withdrawal of 80cc
iv. Patients must have given written informed consent before any study specific procedures

Exclusion criteria

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Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-08-2014
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	08-07-2014
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	17-11-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-04-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-10-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	10-03-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-05-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	

Date:	04-02-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-09-2023
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	NL48824.031.14