Blood sampling of oncology patients treated with monoclonal antibodies

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27631

Source
NTR

Brief title
MULTOMAB

Health condition

All malignancies that are treated with intravenous monoclonal antibodies

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: Erasmus Medical Center

Intervention

Outcome measures

Primary outcome

To set up a bank of prospectively collected blood samples from patients treated with monoclonal antibodies.

Secondary outcome

- To correlate pharmacokinetic (PK) parameters with effectiveness and toxicity of monoclonal antibodies.

- To determine the influence of immunogenicity on PK.

- To determine the influence of peripheral blood immune cell characteristics on PK and effectiveness and toxicity of monoclonal antibodies.

- Explore the characteristics of exosomes before start of treatment, during treatment, and after disease progression.

- To assess the course of PK and PBMC characteristics shortly after the first treatment cycle, i.e. within 1 week.- To validate an assay that can determine serum concentrations of monoclonal antibodies.

Study description

Background summary

To set up a bank of prospectively collected blood samples for pharmacokinetic analyses of monoclonal antibodies and immunophenotyping

Study objective

To set up a bank of prospectively collected blood samples for pharmacokinetic analyses of monoclonal antibodies and immunophenotyping

Study design

Prior to every infusion.

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

• Age ≥18 years

• Able to understand the written information and able to give informed consent

• Planned treatment with (intravenous) monoclonal antibodies for any type of cancer according to standard of care. Monoclonal antibodies include, but are not limited to: cetuximab, nivolumab, ipilimumab, pembrolizumab, bevacizumab, and trastuzumab.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

• Unable to draw blood for study purposes

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-04-2016
Enrollment:	1000
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-02-2018
Application type:	First submission

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
NTR-new	NL6828
NTR-old	NTR7015
Other	: MEC 16-011

Study results