PRospective tumor sampling in oncology patients with solid tumors treated with Immune Modulating Agents

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To set up a biobank of prospectively collected tumor samples for genetic and immunological analysis, prior to and during IMA treatment.

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON54892

Source
ToetsingOnline

Brief title
PRIMA

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
solid malgnancies, solid tumors

Research involving
Human

Sponsors and support

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

Intervention

Keyword: biopsies, cancer, immunotherapy

Outcome measures

Primary outcome

The primary study endpoint is the evaluation of the interaction between genetic and immunological characteristics of a patients tumor and the IMA prescribed.

Secondary outcome

Secondary endpoint includes the determination of immunological and genetic differences in tumor biopsies of patients responding and patients not responding to IMA.

Study description

Background summary

In treatment of solid tumors in oncology, immune modulating agents (IMAs) have become key players. However, only the minority of (thoracic) cancer patients benefits and immune related toxicities can be the harmful consequences of these agents. Reliable biomarkers are therefore urgently needed to guide personalized treatment selection and provide on-treatment indicators. Furthermore, the effects of IMAs on the immune system and on the tumor cells are largely unexplained. Our aim is twofold: first we aim to map the immunological and genetic background of the tumors of patients we plan to treat with IMAs. Second, we aim to sequentially monitor the effects of IMAs on the immunological and genetic characteristics of the tumor and the tumor immune microenvironment (TME).

Study objective

To set up a biobank of prospectively collected tumor samples for genetic and immunological analysis, prior to and during IMA treatment.

Study design

This is a biobank study that will prospectively collect tumor samples. Tumor

samples will be collected before, during and upon progression or regression of disease to treatment.

Study burden and risks

The risks associated with tumor biopsies are low to moderate, considering the fact that only easy accessible tumors or metastases will be biopsied.

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

• Histological or cytological proven solid tumor
• Age >=18 years

• Written informed consent
• Performance score: WHO 0-2 at the time of study entry
• Planned treatment with (intravenous) immune modulating agents for any type of cancer according to standard of care.

Exclusion criteria

• Unable to draw blood for study purposes (e.g. severe anemia Hb <5,5 mmol/L)
• Unable to safely obtain tumor biopsies
• Known human immunodeficiency virus (HIV), chronic hepatitis B or C infection

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	17-06-2020
Enrollment:	350
Type:	Anticipated

Ethics review

Approved WMO

Date:	11-02-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL74235.078.20