Development of blood-based monitoring techniques in lymphatic malignancies

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Development of blood-based monitoring techniques for treatment response evaluation and diagnostics in lymphoid neoplasms, including HL and NHL by using extracellular vesicle and cfDNA techniques for biomarker discovery, assay development and...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON47352

Source
ToetsingOnline

Brief title
BioLymph

Condition

- Other condition
- Lymphomas non-Hodgkin's B-cell
- Lymphomas Hodgkin's disease

Synonym
lymphatic malignancies

Health condition

Lymphoide maligniteiten volgens WHO 2016 classificatie

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: KWF VU2015-8081

Intervention

Keyword: circulating free DNA, liquid biopsy, lymphoma, miRNA-vesicle based diagnostics

Outcome measures

Primary outcome

The main study endpoint is the development of validated blood-based assays for

monitoring disease status in patients with lymphoid neoplasms and correlation

of blood-based assays with PET response during and after treatment.

Secondary outcome

not applicable

Study description

Background summary

The aim of this current study is to develop blood-based monitoring techniques in malignant lymphoma*s. Positron emission tomography (PET) imaging can be used by clinicians to detect increased metabolic activity in tissues and masses. PET is used for evaluation of the extent of the disease and treatment response in non-Hodgkin lymphoma (NHL) and Hodgkin lymphoma (HL). Although PET imaging in general has a high negative predictive value, the downside of PET imaging is a relatively poor positive predictive value and increased radiation burden from repeated scanning for disease monitoring. Hence, there is a clinical need for blood-based monitoring techniques that can be frequently repeated to monitor treatment response and help facilitate personalized treatment per patient. Therefore, blood based methods for monitoring of tumor activity are under development. In a previous study, we were able to detect and quantify genetic disease markers (miRNAs) and protein (TARC) in patient plasma, which levels corresponded with the presence of vital tumor in HL. Hence this method may be an alternative for, or complement to the current PET imaging for monitoring treatment response in lymphoma. Circulating cell free tumor DNA (cfDNA) is another alternative method and is being explored as a

companion-diagnostic or treatment monitoring tool for multiple types of solid tumors but may also serve as an alternative method for treatment monitoring.

Study objective

Development of blood-based monitoring techniques for treatment response evaluation and diagnostics in lymphoid neoplasms, including HL and NHL by using extracellular vesicle and cfDNA techniques for biomarker discovery, assay development and prospective validation.

Study design

Longitudinal observational COHORT study

Study burden and risks

Patients with lymphoid neoplasms will have no direct benefit from participating in this study. The additional burden for participating patients consists of submitting extra blood samples during regular, planned sampling for diagnostic purposes during and after treatment and during follow-up. The patients will be not be subjected to extra visits or extra blood draws outside the planned blood examinations in regular care, thereby not inferring extra risk or additional burden. In patients who undergo a spinal tap for routine diagnostic or monitoring purposes as part of regular care, will be invited to submit an extra tube of CSF (maximum 5 ml) as well for comparison to blood based protocols. This will also not benefit the patients personally but will provide highly valuable information for assay development in selected patient groups.

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

Diagnosed with a lymphoid malignancy as defined in the WHO classification 2016.

Exclusion criteria

Patient is at inclusion also diagnosed with a solid-malignancy, such as breast cancer, colon carcinoma, melanoma or other solid malignancies that requires treatment.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2017
Enrollment:	300

Type:	Actual

Ethics review

Approved WMO Date:	14-03-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-10-2018
Application type:	Amendment
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	NL60245.029.17