' Biomarkers for minimal residual disease in neuro-oncology ': MIRDINO study

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I. Develop and validate method of MRD detection in body fluids with DNA and/or RNA markers in patients with any central nervous system (CNS) tumor at diagnosis, treatment and follow-up.II. Collect tumor tissue, CSF, PB and urine of all patients with...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Observational non invasive

Summary

ID

NL-OMON46208

Source
ToetsingOnline

Brief title
MIRDINO study

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
braintumors

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: aanvraag voor subsidie gedaan bij KIKA en KWF

Intervention

Keyword: Braintumors, Liquid Biopsies, Minimal residual disease (MRD)

Outcome measures

Primary outcome

1. Development of techniques for detection of MRD (PCR: RNA-DNA, next generation sequencing) from any CNS tumor in CSF, PB and urine based on tumor derived expression profiles for candidate genes or DNA aberrations .

2. Compare efficacy of different methods of MRD detection in different body fluids in patients with a CNS tumor.

3. Does MRD at diagnosis and its kinetics during therapy relate with any of the biological subtypes of tumor groups?

4. Does MRD at diagnosis and its kinetics during therapy correlate with treatment outcome?

The endpoint of this study is to determine the presence and, if present, the quantification of MRD in body fluids of patients with a CNS tumor at diagnosis, during treatment and follow-up using different techniques (RQ-PCR, digital PCR and Next generation sequencing of tumor derived abberations) and correlate this with staging and outcome.

Secondary outcome

not applicable

Study description

Background summary

Sensitive diagnostic biomarkers for tumor dissemination and/or progression are still lacking in the clinical process of brain tumors. In this study, named *Biomonitoring of minimal residual disease in neuro-oncology* we investigate whether highly sensitive techniques for specific biomarkers from the tumor in cerebrospinal fluid (CSF) and peripheral blood (PB), and other body fluids like urine, can be developed to:
1. refine the staging of the disease at primary diagnosis (before and after surgery)
2. improve insight in the kinetics of disappearance of minimal residual disease (MRD) in relation to therapy
3. detect (an early) relapse during therapy and follow up

Study objective

I. Develop and validate method of MRD detection in body fluids with DNA and/or RNA markers in patients with any central nervous system (CNS) tumor at diagnosis, treatment and follow-up.
II. Collect tumor tissue, CSF, PB and urine of all patients with a CNS tumor for MRD detection after establishing a valid method

Study design

Observational longitudinal cohort study

Study burden and risks

Nature and extent of the burden and risks:
There are no additional risks and the burden of participation is low, since we will only sample extra blood or CSF, at time points when clinical samples are being sampled. So no extra blood draws or CSF sampling will be done. This study will only take extra 2 millilitres (ml) CSF and/or 5 ml PB and a urine sample at the regular PB and CSF drawings. Primary tumor tissue will be tested by the pathology department to establish a diagnosis, and when there is material left, RNA and DNA will be extracted for study of RNA and DNA markers.

Benefit and group relatedness:
There will not be a benefit for patients participating in this study. However, by participating in this study they help to give insight in the clinical significance of MRD monitoring in CNS tumors and consequently in the possible clinical implementation of MRD in risk stratification and treatment allocation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Radiologicaland if possible histological proven diagnosis of any CNS tumor (M0-M4)
- Any age group
- Written informed consent obtained of the patients and/or their parents or legal guardians

Exclusion criteria

see inclusion criteria

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	400
Type:	Anticipated

Ethics review

Approved WMO

Date:	15-08-2017
Application type:	First submission
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	NL57841.018.16