Primary Cerebral Lymphoma at UMCU and St Antonius

Published: 27-01-2021
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Conducting research into the role of CSF and blood parameters of patients with CNS lymphoma, focused on improving the diagnostics, identification of biomarkers ('liquid biopsy'), and evaluation of therapy effect.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Lymphomas non-Hodgkin's B-cell
Study type	Observational invasive

Summary

ID

NL-OMON54051

Source
ToetsingOnline

Brief title
PRICELUS

Condition

- Lymphomas non-Hodgkin's B-cell
- Nervous system neoplasms malignant and unspecified NEC

Synonym
brain lymphoma, Primary Central Nervous System Lymphoma (PCNSL)

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Stichting Annie van Koeverden

Intervention

Keyword: Cerebrospinal Fluid, Liquid biopsy, Lymphoma, Primary Central nervous system lymphoma

Outcome measures

Primary outcome

Detect specific biomarkers in CSF and/or blood from patients clinically

suspected of primary central nervous system lymphoma. Thereby improving the

diagnosis of CNS lymphoma in a majority of patients and reducing the need for

tissue confirmation through stereotactic biopsy.

Secondary outcome

Possible secondary objectives:

- determine the relationship between the prognosis of CNS lymphoma and specific

biomarkers,

- determine the relationship between specific biomarkers and therapy response.

Study description

Background summary

The current role of CSF diagnostics for CNS lymphoma is acknowledged, but limited to routine cytomorphology and flow cytometry, which can demonstrate lymphoma only in a minority of patients (<25%). Recent research indicates that new CSF markers play a role in diagnosing CNS lymphoma, which has the potential to diagnose CNS lymphoma by CSF investigation, omitting a brain biopsy. Our meta-analysis showed, however, that none of the available CSF markers are sufficiently well investigated to rely upon when making clinical decisions. Whether the evaluation of markers in the blood has additional diagnostic value, has even been investigated to a lesser extent. Moreover, little is known about the role of new CSF markers in the follow-up and therapy evaluation of patients with known CNS lymphoma.

Study objective

Conducting research into the role of CSF and blood parameters of patients with CNS lymphoma, focused on improving the diagnostics, identification of biomarkers ('liquid biopsy'), and evaluation of therapy effect.

Study design

A retrospective and prospective cohort study.

Study burden and risks

Regarding the prospective cohort, there is no extra burden due to participation in this study except for a limited amount of patients for whom the venipuncture is not clinically indicated. For all patients, lumbar puncture is clinically indicated. The amount of CSF additionally drawn is approx. 10 ml and the amount of blood additionally drawn is approx. 67 ml. The risk of participation in this trial is therefore negligible. Patients also have no personal benefit, as the investigation of new biomarkers does not immediately influence current standard clinical care.
Regarding the retrospective cohort, there is no extra burden due to the fact that only CSF is analysed, which had already been drawn from the patients as part of clinical care.

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

1. Suspected or confirmed primary central nervous system lymphoma
2. Age > 18 years
3. Patients who have a clinical indication for a diagnostic lumbar puncture

Exclusion criteria

1) If contra-indications for lumbar puncture are present:
- skin infection
- coagulopathy
- signs or symptoms of increased intracranial pressure
- midline shift or obliteration of basal cisterns on neuro-imaging
2) If a patient is unwilling to give written consent.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-02-2021
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	27-01-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-10-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-03-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL75887.100.20