89Zr-rituximab PET/CT for detection of central nervous system lymphoma

Published: 12-06-2015
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The objective of the study is to confirm that PCNSL is positive on 89Zr-rituximab PET imaging.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lymphomas NEC
Study type	Observational invasive

Summary

ID

NL-OMON42205

Source
ToetsingOnline

Brief title
ZoLa study

Condition

- Lymphomas NEC
- Nervous system neoplasms malignant and unspecified NEC

Synonym
brain tumour, lymphoma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: 89Zr-rituximab PET/CT, central nervous system, lymphoma

Outcome measures

Primary outcome

The main outcome of the study is the performance of 89Zr- rituximab PET/CT in diagnosing CSN lymphoma. The diagnostic gold standard will be histological biopsy and pathology diagnosis of PCNSL.

Secondary outcome

NA

Study description

Background summary

Approximately 2-5% of brain tumours is a primary central nervous system lymphoma (PCSNL), the majority of which are diffuse large-cell B-cell lymphoma. Although PCNSL may have characteristic imaging findings on traditional CT and MR imaging, none of these will unequivocally differentiate CNS lymphoma from other brain lesions. A primary CNS lymphoma cannot, by definition, be diagnosed from sites outside the CNS; only in a minority of patients can cerebrospinal fluid analysis (from lumbar puncture) or ophthalmologic analysis (vitreous body biopsy) provide a diagnosis. Presently, to make the diagnosis, it is necessary to do an invasive biopsy of CNS lymphoma for histopathological analysis. This biopsy only has a diagnostic aim, since - contrary to primary brain tumours - resection does not contribute to outcome in CNS lymphoma1,2. Complications of biopsy, such as bleeding and brain edema are more common in patients with CNS lymphoma than in other primary brain tumours and are seen in 8% of biopsies. One percent of patient will die of complications after biopsy and in 7% of patients it is not possible for the pathologists to make a definite diagnosis of lymphoma 3. With the aid of PET imaging with the tracer 89Zr-rituximab it might be possible to accurately diagnose malignant brain lymphoma. 89Zr-rituximab is a tracer that binds CD20 antigen, a membrane protein. CD-20 is expressed on normal mature B-cell lymphocytes and also on malignant lymphoma cells. If a 89Zr-rituximab PET could adequately predict that a brain tumour is a malignant lymphoma this might prevent some invasive diagnostic biopsies and complications from these invasive biopsies.

Study objective

The objective of the study is to confirm that PCNSL is positive on 89Zr-rituximab PET imaging.

Study design

This prospective diagnostic proof of concept study will investigate 89Zr-rituximab PET uptake in CNS lymphoma.

Study burden and risks

Patients participating in the study will undergo additional 89Zr-rituximab PET imaging before diagnostic brain biopsy. The proposed study is considered safe and well tolerable. The risks of the extra 89Zr-rituximab PET are negligible. The study may lead to insights about the possible added value of using 89Zr-rituximab PET in patients with brain tumours suspicious of primary CNS lymphoma.
There is a very small chance that the extra radiation may lead to adverse health effects. This is a negligible risk.

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

- Patients who have signed informed consent
- Age >= 18 years
- MR suspicion of a primary CNS lymphoma (homogeneous contrast enhancement, low MRI ADC values).

Exclusion criteria

- Pregnancy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-03-2016
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	zirkonium-89 rituximab

Generic name:	89Zr-rituximab

Ethics review

Approved WMO Date:	12-06-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-08-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
EudraCT	EUCTR2015-000056-23-NL
CCMO	NL52204.041.15