Effect of a single dose of 14.8 MBq/kg (0.4 mCi/kg) 90Y-ibritumomab tiuxetan (*Zevalin*) following first-line R-CVP therapy in patients with follicular lymphoma on conversion rate assessed by FDG-PET and on stem cell mobilisation.
A Phase II clinical trial.

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To determine the conversion rate of PR to CR (i.e. PET negativity) after a single dose of 90Y-ibritumomab tiuxetan (a dose of 14.8 MBq/kg or 0.4 mCi/kg, max 1184 MBq or 32mCi) in patients with grade 1-3a, stage II, III or IV follicular lymphoma with...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lymphomas non-Hodgkin's B-cell
Study type	Interventional

Summary

ID

NL-OMON33142

Source
ToetsingOnline

Brief title
Conversion rate after 90Y-ibritumomab tiuxetan following first-line R-CVP

Condition

- Lymphomas non-Hodgkin's B-cell
- Lymphomas non-Hodgkin's B-cell

Synonym
follicular non-Hodgkin's lymphoma, low grade lymphoma

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Bayer

Intervention

Keyword: 90Y-ibritumomab tiuxetan, first line therapy, follicular lymphoma, PET conversion rate

Outcome measures

Primary outcome

the conversion rate of PR to CR

Secondary outcome

progression free survival (PFS)

time to next treatment (TTNT)

biological characteristics in bone marrow and stem cell product before and

after a single dose of 90Y-ibritumomab tiuxetan

Study description

Background summary

90Y-ibritumomab tiuxetan prolongs PFS if given after first line therapy in patients with follicular lymphoma. Untill now it has been given in only a few patients with chemoimmunotherapy as first line, whereas the addition of rituximab to first line therapy is now standard treatment. Remissionstatus is assessed by PET-CT scanning because PET is the better predictor of progression free survival. Because information about the possibiliy of stem cell harvest after 90Y -ibritumomab tiuxetan is lacking, stem cell mobilisation will be done before and after the administration of 90Y-ibritumomab tiuxetan.

Study objective

To determine the conversion rate of PR to CR (i.e. PET negativity) after a single dose of 90Y-ibritumomab tiuxetan (a dose of 14.8 MBq/kg or 0.4 mCi/kg, max 1184 MBq or 32mCi) in patients with grade 1-3a, stage II, III or IV follicular lymphoma with PET-positive partial remission on PET-CT scan following first line R-CVP therapy.
Also, PFS and TTNT will be determined. Biological characteristics of bone marrow and stem cell harvest before and after a single dose of 90Y-ibritumomab tiuxetan will be compared.

Study design

Patients in PET positive PR after induction treatment with R-CVP receive a single dose of 90Y-ibritumomab tiuxetan. If younger than 61 years, stem cell mobilisation will be performed before this. 3 months after the 90Y-ibritumomab tiuxetan a PET-CT scan will be made to assess conversion rate, this will only be repeated after 6 months if CR is not reached at 3 months. Minimal three months after 90Y-ibritumomab tiuxetan a second stem cell mobilisation will be performed.

Intervention

a single dose of 90Y-ibritumomab tiuxetan

Study burden and risks

extra PET-CT scans instead of CT scans
once extra stemcell mobilisation

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

* Histologically confirmed (according to WHO classification) CD 20 positive follicular lymphoma, grade 1, 2 or 3a, stage II, III or IV (with indication for treatment following local guidelines) of all FLIPI scores.
* Age 18 years or older, for stem cell mobilisation analysis age 18-61 years
* Having received 6-8 courses of 1st line R-CVP therapy
* WHO performance status 0 to 2
* Life expectancy of at least 6 months
* PET positive partial remission on PET-CT scan after 6-8 R-CVP
* Absolute neutrofil count (ANC) 1.5 x 109/l or higher
* Platelet count of 150 x 109/l or higher
* Hb > 6 mmol/l, (transfusion is allowed to achieve this)
* Less than 25% bone marrow involvement after 6-8 R-CVP, measured by bone marrow biopsy.
* Written informed consent obtained according to local guidelines

Exclusion criteria

* Any other anticancer treatment for NHL except the first line R-CVP
* Prolonged cytopenia during first line induction chemotherapy requiring more than 2 weeks delay due to insufficient bone marrow reserve.
* Prior external beam radiotherapy to > 25% of active bone marrow. (involved field or regional)
* Patients who have not recovered from the toxic effects of the first line chemotherapy
* Presence of gastric, central nervous system or testicular localisation at first diagnosis
* Any other malignancy or history of prior malignancy except non-melanoma skin cancer or stage 0 cervical carcinoma within the past 10 years
* Patients with pleural effusion or ascites

* Patients with abnormal liver function (bili > 1.5 ULN or ALAT > 2.5 ULN)
* Active uncontrolled infection
* Known diagnosis of HIV infection
* Patients with abnormal renal function: serum creatinine > 2.5 ULN
* Known hypersensitivity to murine antibodies or proteins
* G-CSF or GM-CSF therapy within 2 weeks (or 4 weeks if pegylated) prior to adminstration of 90Y-Ibritumomab tiuxetan
* Female patients who are pregnant or breast feeding, or adults of reproductive potential not employing an effective method of birth control during study treatment and for at least 12 months thereafter
* Concurrent severe and/or uncontrolled medical disease which could compromise study participation
* Patients who received any investigational drugs or underwent surgery less than 4 weeks before entry in this study or who have as yet not recovered from the side-effects of such treatment.
* Patients with a history of psychiatric illness or condition which could interfere with their ability to understand the requirements of this study
* Patients unwilling or unable to comply with the protocol

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-11-2009
Enrollment:	31
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	Zevalin
Generic name:	90Y-ibritumommab tiuxetan
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	26-06-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-07-2009
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
EudraCT	EUCTR2009-012944-17-NL
CCMO	NL28368.029.09