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.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28762

Source
NTR

Brief title
N/A

Health condition

follicular lymphoma/folliculair lymfoom
first line therapy/eerstelijnsbehandeling
90Y-ibritumomab tiuxetan

Sponsors and support

Primary sponsor: Vumc, hematology department

Source(s) of monetary or material Support: sponsor

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. To estimate progression free survival (PFS);

2. To estimate time to next treatment (TTNT);

3. To compare biological characteristics of bone marrow and stem cell harvest before and after a single dose of 90Y-ibritumomab tiuxetan.

Study description

Background summary

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, to compare biological characteristics of bone marrow and stem cell harvest before and after a single dose of 90Y-ibritumomab tiuxetan.

Study objective

Zevalin consolidation after first line therapy with
R-CVP in patients with follicular lymphoma grade 1-3a, stage 2-4 induces conversion of PET positive PR to CR in more than 40% of patients.

Study design

Conversion rate assessed by PET CT scan 3 months (and if still positive) six months after 90Y-

ibritumomab tiuxetan. Stem cell mobilisation before and three months after 90Y-ibritumomab tiuxetan.

Intervention

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.

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Eligibility criteria

Inclusion criteria

1. 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;

2. Age 18 years or older, for stem cell mobilisation analysis age 18-61 years;

3. Having received 6-8 courses of 1st line R-CVP therapy;

4. WHO performance status 0 to 2;

5. Life expectancy of at least 6 months;

6. PET positive partial remission on PET-CT scan after 6-8 R-CVP;

7. Absolute neutrofil count (ANC) 1.5 x 109/l or higher;

8. Platelet count of 150 x 109/l or higher;

9. Hb > 6 mmol/l, (transfusion is allowed to achieve this);

10. Less than 25% bone marrow involvement after 6-8 R-CVP, measured by bone marrow biopsy;

11. Written informed consent obtained according to local guidelines.

Exclusion criteria

1. Any other anticancer treatment for NHL except the first line R-CVP;

2. Prolonged cytopenia during first line induction chemotherapy requiring more than 2 weeks delay due to insufficient bone marrow reserve;

3. Prior external beam radiotherapy to > 25% of active bone marrow. (involved field or regional);

4. Prior myeloablative therapy;

5. Patients who have not recovered from the toxic effects of the first line chemotherapy;

6. Presence of gastric, central nervous system or testicular localisation at first diagnosis;

7. Any other malignancy or history of prior malignancy except non-melanoma skin cancer or stage 0 cervical carcinoma within the past 10 years;

8. Patients with pleural effusion or ascites;

9. Patients with abnormal liver function (bili > 1.5 ULN or ALAT > 2.5 ULN);

10. Active uncontrolled infection;

11. Known diagnosis of HIV infection;

12. Patients with abnormal renal function: serum creatinine > 2.5 ULN;

13. Known hypersensitivity to murine antibodies or proteins;

14. G-CSF or GM-CSF therapy within 2 weeks (or 4 weeks if pegylated) prior to adminstration of 90Y-Ibritumomab tiuxetan;

15. 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;

16. Concurrent severe and/or uncontrolled medical disease which could compromise study participation;

17. 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;

18. Patients with a history of psychiatric illness or condition which could interfere with their ability to understand the requirements of this study;

19. Patients unwilling or unable to comply with the protocol.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-08-2009
Enrollment:	31
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-07-2009
Application type:	First submission

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
NTR-new	NL1798
NTR-old	NTR1908
Other	METC VU MC : 09/173
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A