Efficacy and safety of a single dose of 14.8 MBq/kg (0.4 mCi/kg)90Y-ibritumomab tiuxetan ("Zevalin") in elderly patients with diffuse large B-cell lymphoma and FDG-PET positive partial remission following first-line R-CHOP therapy. A Phase II clinical trial (HOVON 77).

No registrations found.

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

Summary

ID

NL-OMON22777

Source
Nationaal Trial Register

Brief title
HOVON 77 NHL

Health condition

Non-Hodgkin's lymphoma (NHL), B-Cell lymphoma

Sponsors and support

Primary sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
P/a HOVON Data Center
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Source(s) of monetary or material Support: Koningin Wilhelmina fonds (KWF), Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON), Bayer Schering Pharma

Intervention

Outcome measures

Primary outcome

Response on FDG-PET (i.e. PET-negative residual masses).

Secondary outcome

1. Progression-free survival;

2. Overall survival;

3. Toxicity CTC AE grade 3-4.

Study description

Background summary

Study phase: Phase II.

Study objective: Evaluation of efficacy and safety of 90Y-ibritumomab tiuxetan.

Patient population: Patients with Diffuse Large B-Cell lymphoma, CD20-positive, age ¡Ý 60 years and good WHO performance status (0,1,2), with PET-positive PR after R-CHOP induction chemotherapy.

Study design: Prospective, multicenter, open label, non-randomized.

Duration of treatment: Infusion of rituximab followed 1 week later by a second rituximab infusion and a single dose of 90Y-ibritumomab tiuxetan.

Study objective

The hypothesis to be tested is that the efficacy and toxicity of treatment with 90Y-ibritumomab tiuxetan meets the expectations as described in the protocol.

Study design

At entry, 3 months after treatment, 6 months after treatment or at time of disease progression, in FU every 3 months during first 2 years, every 6 months during the next 2 years and annually thereafter.

Intervention

Infusion of Rituximab followed one week later by a second Rituximab infusion and a single dose of 90Y-ibritumomab tiuxetan.

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Eligibility criteria

Inclusion criteria

1. Age >= 60 years old;

2. WHO performance status of 0-2;

3. Life expectancy of at least 3 months;

4. Histologically confirmed CD20 positive Diffuse large B-cell lymphoma (DLBCL), according to the WHO classification;

5. First-line induction treatment with R-CHOP or R-CHOP-like chemotherapy (only CHOP in combination with rituximab; CHOP14 and CHOP21 are both allowed);

6. Partial response on CT-scans after first-line treatment, with measurable disease;

7. PET-positive residual mass;

8. Patient is not eligible for high dose chemotherapy followed by autologous stem cell transplantation;

9. Less than 25% bone marrow involvement at the end of first-line treatment during PR analysis (measurement in a representative bone marrow biopsy);

10. Absolute neutrophil count (ANC) >= 1.5x10^9/l;

11. Hemoglobin (Hb) >= 6 mmol/l;

12. Platelets >= 150 x 10^9/l;

13. Written informed consent obtained according to local guidelines.

Exclusion criteria

1. Hypoplastic bone marrow at biopsy;

2. Prolonged pancytopenia during induction chemotherapy and delayed courses during R-CHOP induction (more than two weeks delay due to insufficient bone marrow reserve);

3. Known hypersensitivity to murine antibodies or proteins;

4. Significant splenomegaly;

5. Patients with abnormal liver function (total bilirubin > 2.0 x ULN);

6. Patients with abnormal renal function (serum creatinine > 2.0 x ULN);

7. Presence of CNS involvement by NHL;

8. Presence of any other active neoplasms or history of prior malignancy, except non-melanoma skin tumours or stage 0 (in situ) cervical carcinoma during the past 5 years;

9. More than one prior R-CHOP or R-CHOP-like chemotherapy regimen for DLBCL;

10. Patients who have received prior external beam radiotherapy to > 25% of active bone marrow (involved field or regional);

11. Patients who have received G-CSF or GM-CSF therapy within two weeks prior to study enrollment;

12. Concurrent severe and/or uncontrolled medical condition (e.g. uncontrolled diabetes, congestive heart failure, myocardial infarction within 6 months of study, unstable and uncontrolled hypertension, chronic renal disease, or active uncontrolled infection) which could compromise participation in the study;

13. Patients who have received biologic therapy, immunotherapy, R-CHOP(-like) chemotherapy, surgery, or an investigational drugs less than 4 weeks prior to first day of study treatment or who have not recovered from the toxic effects of such therapy;

14. Patients who have received systemic corticosteroids at doses higher than 20 mg/day prednisolone or equivalent less than 2 weeks prior to 90Y-ibritumomab tiuxetan administration;

15. Known diagnosis of HIV infection;

16. 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:	Recruiting
Start date (anticipated):	05-01-2006
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-10-2009
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	NL1969
NTR-old	NTR2086
Other	EudraCT number : 2005-003796-20
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A