Phase II study on the feasibility and efficacy of consolidation with 90Y-ibritumomab tiuxetan in patients with relapsed or refractory aggressive B-cell non-Hodgkin’s lymphoma having achieved partial or complete remission after induction with R-PECC chemotherapy.

No registrations found.

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

Summary

ID

NL-OMON24909

Source
Nationaal Trial Register

Brief title
HOVON 85 NHL

Health condition

Aggressive B-cell NHL: FL grade 3b and DLBCL

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: HOVON receives unrestricted grants and/or financial support from Amgen, BSP, Johnson&Johnson-Orthobiotech, Roche and Novartis for the execution of investigator sponsored trials. In addition HOVON is supported by the Dutch Cancer Society.

Intervention

Outcome measures

Primary outcome

- The incidence of grade >=3 adverse events after treatment with 90Y-ibritumomab tiuxetan.

- Failure free survival measured from the start of 90Y-ibritumomab tiuxetan

Secondary outcome

- Incidence and duration of hypoplasia after treatment with 90Y-ibritumomab tiuxetan

- Incidence of adverse events after treatment with 90Y-ibritumomab tiuxetan

- Incidence of adverse events after treatment with R-PECC

- Percentage of patients treated with R-PECC who proceed to 90Y-ibritumomab tiuxetan treatment

- Conversion to PET negative CR after 90Y-ibritumomab tiuxetan treatment of patients who are PET positive before start of 90Y-ibritumomab tiuxetan

- Overall survival measured from the start of 90Y-ibritumomab tiuxetan

- Response rates to R-PECC and response duration

- Failure free survival and overall survival measured from the start of R-PECC

Study description

Background summary

Study phase: II

Study objective:

Evaluation of feasibility and efficacy of consolidation with 90Y-ibritumomab tiuxetan in patients with relapsed or refractory aggressive B-cell non-Hodgkin’s lymphoma (NHL) having achieved partial or complete remission after induction with R-PECC chemotherapy

Patient population:
Patients with histologically confirmed CD20 positive aggressive NHL (FL grade 3b, DLBCL) refractory or in first or second relapse, age > 18 years with WHO performance status 0-2, after / not eligible for autologous stem cell transplantation (ASCT)

Study design:
Prospective, multicenter, non-randomized

Duration of treatment:
Expected duration of treatment is about 5-6 months

Study objective

Addition of 90Y-ibritumomab tiuxetan after R-PECC is feasible and the efficacy meets expectations as described in the protocol.

Study design

- prior to start treatment
- after 2 cycles of R-PECC

- after 4 cycles of R-PECC

- after 90 Y-ibritumomab tiuxetan treatment

- in follow-up every 2 months during the first year, every 4 months during the second year and every 6 months thereafter

Intervention

Patients will be treated with R-PECC (rituximab, lomustine, etoposide, chlorambucil, prednisone) and 90Y-ibritumomab tiuxetan.

All patients, who have not attained at least a stable disease after 2 cycles of R-PECC and a PR

after 4 cycles of R-PECC, will go off protocol treatment.

Patients in PR or CR after 4 cycles of R-PECC will be treated with a single dose of 90Y-ibritumomab tiuxetan.

A cytoreductive pre-phase is permitted.

Contacts

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Eligibility criteria

Inclusion criteria

1. Histologically confirmed aggressive B-cell NHL according to the World Health Organization (WHO) classification: Follicular lymphoma grade 3b or Diffuse large B-cell lymphoma

2. Refractory disease or histologically confirmed first or second relapse(Refractory is defined as no response or partial remission according to CT. Patients in partial response (PR) can only be included in case of positive PET scan or positive biopsy)

3. CD20 positive (assessed at 1st diagnosis or from fresh histology at confirmation of relapse or immunophenotyping of circulating CD20-positive NHL cells from peripheral blood)

4. Current measurable disease, i.e. measurable in two perpendicular dimensions on physical examination or computerized tomography (CT) scan using standardized response criteria for NHL (Cheson et al, 1999)

5. Age > 18 years

6. WHO performance status 0, 1 or 2

7. Life expectancy of at least 3 months

8. Absolute neutrophil count > 1.5 x 109/l and platelet count > 100 x 109/l (unless caused by NHL infiltration in the bone marrow)

9. Written informed consent

Exclusion criteria

1. Prior allogeneic stem cell transplantation-

2. Prior radioimmunotherapy

3. Patients who have received chemotherapy or radiotherapy within 6 weeks prior to study entry or who have not recovered from toxicities related to prior therapies

4. Eligibility for ASCT- ASCT within 12 months of study entry

5. Investigational drugs within 4 weeks prior to entry on this study or persistent toxic side effects of such therapy

6. Treatment with external-beam radiation therapy to more than 25% of active bone marrow

7. A history of intolerance to rituximab

8. Severe cardiac, pulmonary, neurological, psychiatric or metabolic disease which could compromise participation in the study, or serious underlying medical conditions which could impair the ability of the patient to participate in the trial

9. Hepatic dysfunction, bilirubin or transaminases >= 2.5 x upper normal limit (unless caused by the NHL)

10. Renal dysfunction, serum creatinine >=180 mmol/l or clearance <= 40 ml/min (unless caused by the NHL)

11. Active uncontrolled infections

12. Patients known to be HIV-positive

13. Current or chronic hepatitis B or hepatitis C infection

14. Symptomatic NHL localization in the central nervous system (CNS). Lumbal puncture is not required unless CNS involvement with NHL is clinically suspected

15. Transformed indolent lymphoma

16. Post-transplant lymphoproliferative disorder

17. Pregnant or breast-feeding female patients. Negative serum pregnancy test at study is mandatory for female patients of childbearing potential

Study design

Design

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

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2008
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-07-2008
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	NL1330
NTR-old	NTR1380
Other	: H085
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A