Randomized phase III study on the effect of early intensification of rituximab in combination with 2-weekly CHOP chemotherapy followed by rituximab maintenance in elderly patients (66-80 years) with diffuse large B-cell lymphoma

No registrations found.

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

Summary

ID

NL-OMON23148

Source
NTR

Brief title
HOVON 84 NHL

Health condition

Diffuse large B-cell lymphoma

Sponsors and support

Primary sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
P/a HOVON Data Center
Erasmus MC - Daniel den Hoed
Postbus 5201
3008 AE Rotterdam
Tel: 010 4391568
Fax: 010 4391028

e-mail: hdc@erasmusmc.nl
Source(s) of monetary or material Support: HOVON receives unrestricted grants and/or financial support from Amgen, 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

First randomization:
- Response rate (complete remission and FDG-PET negative partial remission or unconfirmed complete remission)
Second randomization:
- Failure free survival (measured from the date of second randomization)

Secondary outcome

First randomization:
- Failure free survival measured from the date of registration. Patients still alive or lost to follow up are censored at the last day they were known to be alive
- Overall survival measured from the time of registration
- Time to reach response
- Toxicity
Second randomization:
- Overall survival
- Toxicity

Study description

Background summary

Study phase: Phase III
Study objectives: To evaluate the efficacy of:
- early intensification of rituximab combined with 2-weekly CHOP+G-CSF (R-CHOP14) in remission induction treatment in comparison to standard R-CHOP14;
- maintenance treatment with rituximab in patients in remission after R-CHOP14 in comparison to no further treatment.
Patient population: Patients with stage II-IV diffuse large B-cell lymphoma (DLBCL), CD20 positive, previously untreated, age 66-80 years and WHO performance status 0-2.
Study design: Prospective, multi center, randomized.

Duration of treatment: Expected duration of remission induction treatment is 16 weeks. For patients randomized to maintenance treatment the additional treatment time is 2 years

Study objective

First randomization: The hypothesis to be tested is that the outcome in arm B (early intensification of rituximab combined with 2 weekly CHOP) is better than in arm A (no intensification of rituximab).
Second randomization: The hypothesis to be tested is that the outcome in arm 2 (maintenance treatment with Rituximab) is better than in arm 1 (no futher treatment).

Intervention

Arm A: 8 cycles of R-CHOP14 plus
G-CSF: pegfilgrastim (Neulasta)
Arm B 8 cycles of R-CHOP14 plus
G-CSF: pegfilgrastim (Neulasta) with intensification of rituximab (MabThera) during the first 4 cycles.

Arm 1: no further treatment
Arm 2: maintenance treatment with rituximab (MabThera) once every 8 weeks until relapse (for a maximum period of 24 months)

Contacts

Public
Erasmus MC
Afd. Hematologie
Postbus 2040

P.J. Lugtenburg
Rotterdam 3000 CA
The Netherlands
+31 (0)10 4633123
Scientific
Erasmus MC
Afd. Hematologie
Postbus 2040

P.J. Lugtenburg
Rotterdam 3000 CA
The Netherlands
+31 (0)10 4633123

Eligibility criteria

Inclusion criteria

1. Patients with a confirmed histologic diagnosis of diffuse large B-cell lymphoma (DLBCL) based upon a representative histology specimen according to the WHO classification
2. DLBCL must be CD20 positive
3. Ann Arbor stages II-IV
4. ≥ 66 and £ 80 years
5. Age WHO performance status 0 – 2
6. Written informed consent

Exclusion criteria

1. Intolerance of exogenous protein administration
2. Severe cardiac dysfunction (NYHA classification III-IV or LVEF < 45%. Congestive heart failure or symptomatic coronary artery disease or cardiac arrhythmias not well controlled with medication. Myocardial infarction during the last 6 months
3. Severe pulmonary dysfunction (vital capacity or diffusion capacity < 50% of predicted value) unless clearly related to NHL involvement
4. Patients with uncontrolled asthma or allergy, requiring systemic steroid treatment
5. Significant hepatic dysfunction (total bilirubin ≥30mmol/l or transaminases ≥ 2.5 x upper normal limit), unless related to NHL
6. Significant renal dysfunction (serum creatinine ≥ 150 umol/l or clearance ≤ 60 ml/min), unless related to NHL
7. Clinical signs of severe cerebral dysfunction
8. Suspected or documented Central Nervous System involvement by NHL
9. Patients with a history of uncontrolled seizures, central nervous system disorders or psychiatric disability judged by the investigator to be clinically significant and adversely affecting compliance to study drugs
10. Testicular DLBCL
11. Primary mediastinal B cell lymphoma
12. Transformed indolent lymphoma
13. (EBV) post-transplant lymphoproliferative disorder
14. Secondary lymphoma after previous chemotherapy or radiotherapy
15. Major surgery, other than diagnostic surgery, within the last 4 weeks
16. Patients with active uncontrolled infections
17. Patients known to be HIV-positive
18. Active chronic hepatitis B or C infection
19. Serious underlying medical conditions, which could impair the ability of the patient to participate in the trial (e.g. ongoing infection, uncontrolled diabetes mellitus, gastric ulcers, active autoimmune disease)
20. Life expectancy < 6 months

21. Prior treatment with chemotherapy, radiotherapy or immunotherapy for this lymphoma, except a short course of prednisone (< 1 week) and/or cyclophosphamide (< 1 week and not in excess of 900 mg/m2 cumulative) or local radiotherapy in order to control life threatening tumor related symptoms
22. History of active cancer during the past 5 years, except basal carcinoma of the skin or stage 0 cervical carcinoma

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2007
Enrollment:	550
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-07-2007
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	NL986
NTR-old	NTR1014
Other	: HO84
ISRCTN	ISRCTN82286322

Study results

Summary results

-