A randomized phase III study of chimeric anti-CD20 monoclonal antibody (Rituximab) with 2-weekly CHOP chemotherapy (CHOP 14) in elderly patients with intermediate- or high-risk non-Hodgkin’s lymphoma.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28411

Source
NTR

Brief title
HOVON 46 NHL

Health condition

Non Hodgkin’s 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: - Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
- Koningin Wilhelmina Fonds (KWF)

Intervention

Outcome measures

Primary outcome

Event-free survival (i.e. time from registration to induction failure (i.e. no CR or CRu on induction treatment), death or relapse whichever occurs first); the time to failure of patients with induction failure is set at one day.

Secondary outcome

1. Complete response;

2. Overall survival measured form the time of registration;

3. Disease-free interval (duration of the first CR) measured from the time of achievement of CR to day of relapse or death from any cause (whichever occurs first);

4. Toxicity.

Study description

Background summary

Study phase: phase III

Study objective: evaluation of the effect of anti-CD20 (Rituximab) combined with 2-weekly CHOP + G-CSF in comparison to 2-weekly CHOP + G-CSF alone

Patient population: patients with intermediate- or high-risk NHL (MCL, Follicular Lymphoma grade III or DLBCL), CD20-positive, previously untreated, age >= 65 years and good WHO performance status (WHO 0-2)

Study design: prospective, multicenter, randomized

Duration of treatment: expected duration of treatment is 16 weeks.

Study objective

The hypothesis to be tested is that the outcome in arm B is better than in arm A.

Study design

N/A

Intervention

Patients will be randomized between:

Arm A:
8 cycles of CHOP q 2 weeks plus G-CSF (pegfilgrastim, Neulasta®) once per cycle;

Arm B:
8 cycles of CHOP q 2 weeks plus G-CSF (pegfilgrastim, Neulasta®) once per cycle combined with 6 administrations of Rituximab (Mabthera®).

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with a confirmed histologic diagnosis of NHL according to the WHO classification: Mantle cell lymphoma (MCL), Follicular lymphoma (grade III) (FL III) or Diffuse large B-cell lymphoma (DLBCL);

2. Low-intermediate, high-intermediate or high risk NHL according to age-adjusted IPI score;

3. NHL must be CD20 positive;

4. Age 65 years or more;

5. WHO performance status 0-2;

6. Written informed consent.

Exclusion criteria

1. Intolerance of exogenous protein administration;

2. Severe cardiac dysfunction (NYHA classification II-IV) or LVEF < 45 %;

3. Significant renal dysfunction (serum creatinine >= 150 mmol/l), unless related to NHL;

4. Significant hepatic dysfunction (total bilirubin >= 30 mmol/l or transaminases >= 2.5 times normal level), unless related to NHL;

5. Suspected or documented Central Nervous System involvement by NHL;

6. Patients known to be HIV-positive;

7. Patients with active, uncontrolled infections;

8. Patients with uncontrolled asthma or allergy, requiring steroid treatment

ior treatment with chemotherapy, radiotherapy or immunotherapy for this lymphoma, except local radiotherapy in case of (potential) organ dysfunction by localized lymphoma mass or infiltration

story 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
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-11-2001
Enrollment:	400
Type:	Actual

Ethics review

Positive opinion

Date:	05-09-2005
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	NL149
NTR-old	NTR184
Other	: Ho46
ISRCTN	ISRCTN84611849

Study results

Summary results
N/A