Intensified CHOP of 12-weeks duration plus G-CSF as compared with standard CHOP of 24-weeks duration for patients with intermediate-prognosis Non Hodgkin’s Lymphoma.

No registrations found.

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

Summary

ID

NL-OMON28643

Source
NTR

Brief title
HOVON 26 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

CR rate and overall survival.

Secondary outcome

1. Disease-free survival;

2. Relapse rate;

3. Assessment of value of risk factors at diagnosis in relation to dose intensity of the treatment;

4. Morbidity, nr of days in hospital, treatment-related mortality, duration of leucopenia and other aspects in relation to dose intensity.

Study description

Background summary

Study phase:

phase III.

Study objective:

evaluation of the effect of intensified CHOP q 2 weeks + G-CSF with respect to CR rate and disease-free and overall survival.

Patient population:

patients with primary NHL (groups D,E,F,G,H), intermediate risk, age 15-65 years inclusive.

Study design: prospective, multicenter, randomized.

Duration of treatment:

expected duration of treatment is 24 weeks for arm A and 12 weeks for arm B.

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:

3 courses of standard CHOP q 3 weeks.

Arm B:

3 courses of intensified CHOP q 2 weeks plus G-CSF.

Patients with less than PR will go off protocol. Patients in PR or CR will proceed to another 5 courses of standard CHOP or another 3 courses of intensified CHOP plus G-CSF.

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Eligibility criteria

Inclusion criteria

1. Previously untreated patients with a primary NHL of intermediate- or high-grade malignancy according to the Working Formulation (group D,E,F,G,H);

2. Belonging to the intermediate risk group: stage II, LDH >=1.5x normal; stage III, LDH >1.5x normal; stage IV, LDH <1.5x normal;

3. Age >=15 <=65 years.

Exclusion criteria

1. Patients with prior malignancies, except stage 1 cervix carcinoma and basocellular carcinoma;

2. Patients with severe cardiac (means severe heart failure requiring symptomatic treatment or a cardiac ejection fraction of < 45%) pulmonary, neurologic or metabolic disease- Inadequate liver or renal function, i.e. serum creatinine or bilirubin > 2.5x the upper normal value, except when related to the lymphoma;

3. HIV positivity;

4. Inability to give informed consent;

5. Involvement of the central nervous system by the NHL.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-11-1994
Enrollment:	513
Type:	Actual

Ethics review

Positive opinion

Date:	06-09-2005
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	NL202
NTR-old	NTR239
Other	: Ho26
ISRCTN	ISRCTN11397785

Study results

Summary results
Blood. 2007 Apr 1;109(7):2759-66.