Effect of recombinant G-CSF on the results of chemotherapy (CHOP) in elderly patients with intermediate-/high-grade Non-Hodgkin’s Lymphoma. A prospective phase III study.

No registrations found.

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

Summary

ID

NL-OMON22855

Source
NTR

Brief title
HOVON 25 NHL

Health condition

Non-Hodgkin’s Lymphoma.

Sponsors and support

Primary sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
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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 Organisation CKTO.

Intervention

Outcome measures

Primary outcome

CR rate.

Secondary outcome

1. Relapse rate;

2. Event-free survival;

3. Overall survival;

4. Treatment-related morbidity;

5. Therapy-related hospital admissions;

6. Mortality.

Study description

Background summary

Study phase: phase III;

Study objective:

Evaluation of the effect of G-CSF on response and survival of NHL to therapy. Evaluation of the effect of prophylactic G-CSF on treatment-related morbidity and mortality. Evaluation of possible beneficial effect of G-CSF on patient adherence to Relative Dose Intensity of the standard therapy.

Patient population:

Patients with previously untreated NHL, stage II-IV, intermediate or high grade, age >= 65 years.

Study design:

prospective, multicenter, randomized;

Duration of treatment:

Expected duration of treatment is maximally 8 months.

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 at entry between:

Arm A: CHOP q 3 weeks, 6 or 8 courses;

Arm B: CHOP q 3 weeks, 6 or 8 courses + 300 mcg s.c. daily. G-CSF

CHOP consists of cyclophosphamide, doxorubicin, vincristine and prednisone.

Contacts

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Eligibility criteria

Inclusion criteria

1. Previously untreated Non-Hodgkin’s Lymphoma;

2. Ann Arbor stage II, III or IV;

3. Intermediate- or high grade malignancy (Working Formulation), confirmed by histology;

4. Age >= 65 years;

5. Informed consent.

Exclusion criteria

1. Treatment for NHL with chemotherapy or radiotherapy (local irradiation to life-threatening tumor infiltration is allowed);

2. Lymphoblastic lymphoma;

3. Other malignant diseases, except localized squamous skin carcinoma;

4. Severe heart failure requiring symptomatic treatment or a cardiac ejection fraction of less than 45%;

5. Inadequate liver or renal function, i.e. serum creatinine or serum bilirubin > 1.5x the upper normal value, except when related to lymphoma organ infiltration;

6. HIV positivity.

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):	01-08-1994
Enrollment:	410
Type:	Actual

Ethics review

Positive opinion

Date:	09-09-2005
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	NL282
NTR-old	NTR320
Other	: HO25
ISRCTN	ISRCTN26340837

Study results

Summary results

1. J.K. Doorduijn, I. Buijt, B. van der Holt, M. van Agthoven, P. Sonneveld and C.A. Uyl-de Groot. Economic evaluation of prophylactic granulocyte colony stimulating factor during chemotherapy in elderly patients with aggressive non-Hodgkin's lymphoma. Haematologica, 89(9), 1109-1117. 2004;
2. J.K. Doorduijn, B. van der Holt, G.W. van Imhoff, K.G. van der Hem, M.H.H. Kramer, M.H.J. van Oers, G.J. Ossenkoppele, M.R. Schaafsma, L.F. Verdonck, G.E.G. Verhoef, M.M.C. Steijaert, I. Buijt, C.A. Uyl-de Groot, M. van Agthoven, A.H. Mulder and P. Sonneveld for the Dutch-Belgian Hemato-Oncology Cooperative Group (HOVON). CHOP compared with CHOP plus granulocyte colony-stimulating factor in elderly patients with aggressive non-Hodgkin's lymphoma. Journal of Clinical Oncology, 21(16), 3041-3050. 2003.