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.

Gepubliceerd: 09-09-2005 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22855

Bron
NTR

Verkorte titel
HOVON 25 NHL

Aandoening

Non-Hodgkin’s Lymphoma.

Ondersteuning

Primaire 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

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

CR rate.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

P.O. Box 2040
P. Sonneveld
Erasmus University Medical Center,
Department of Hematology
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7033589

Wetenschappelijk

P.O. Box 2040
P. Sonneveld
Erasmus University Medical Center,
Department of Hematology
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7033589

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-08-1994
Aantal proefpersonen:	410
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL282
NTR-old	NTR320
Ander register	: HO25
ISRCTN	ISRCTN26340837

Resultaten

Samenvatting resultaten

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.