

Effect of recombinant Granulocyte Colony-Stimulating Factor (G-CSF) on the results of chemotherapy (CHOP) in elderly patients with intermediate-/high-grade Non-Hodgkin's Lymphoma: a prospective phase III study

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/11/2007	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.hovon.nl>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HO25

Study information

Scientific Title

Acronym

HOVON 25 NHL

Study objectives

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

Objectives:

1. Evaluation of the effect of G-CSF on response and survival of Non-Hodgkin's Lymphoma (NHL) to therapy
2. Evaluation of the effect of prophylactic G-CSF on treatment-related morbidity and mortality
3. Evaluation of possible beneficial effect of G-CSF on patient adherence to Relative Dose Intensity of the standard therapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Multicentre, randomised, active controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Non Hodgkin's Lymphoma (NHL)

Interventions

Patients will be randomised at entry between:

Arm A: CHOP every 3 weeks, 6 or 8 courses

Arm B: CHOP every 3 weeks, 6 or 8 courses and 300 mcg subcutaneous (s.c.) daily G-CSF

CHOP consists of cyclophosphamide, doxorubicin, vincristine and prednisone.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Granulocyte Colony-Stimulating Factor (G-CSF), cyclophosphamide, doxorubicin, vincristine and prednisone (CHOP)

Primary outcome measure

Complete Remission (CR) rate.

Secondary outcome measures

1. Relapse rate
2. Event-free survival
3. Overall survival
4. Treatment-related morbidity
5. Therapy-related hospital admissions
6. Mortality

Overall study start date

01/08/1994

Completion date

05/09/2000

Eligibility**Key inclusion criteria**

1. Previously untreated Non-Hodgkins Lymphoma
2. Ann Arbor stage II, III or IV
3. Intermediate- or high grade malignancy (Working Formulation), confirmed by histology
4. Aged greater than or equal to 65 years
5. Informed consent

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

410

Key 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, ie serum creatinine or serum bilirubin > 15x the upper normal value, except when related to lymphoma organ infiltration
6. HIV positivity

Date of first enrolment

01/08/1994

Date of final enrolment

05/09/2000

Locations

Countries of recruitment

Netherlands

Study participating centre

Erasmus University Medical Centre

Rotterdam

Netherlands

3000 CA

Sponsor information

Organisation

Dutch Haemato-Oncology Association (Stichting Hemato-Oncologie Volwassenen Nederland) (HOVON) (Netherlands)

Sponsor details

Vrije University Medical Centre (VUMC)

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+31 (0)20 444 2693
hdc@hovon.nl

Sponsor type

Research organisation

Website

<http://www.hovon.nl/>

ROR

<https://ror.org/056kpdx27>

Funder(s)

Funder type

Industry

Funder Name

Johnson & Johnson (The Netherlands)

Alternative Name(s)

Johnson & Johnson, johnson & Johnson Services, Inc., Johnson&Johnson, , Johnson & Johnson Private Limited, , J&J, JNJ

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

Commission for Medical Applied Research (Commissie voor Klinisch Toegepast Onderzoek [CKTO]) (The Netherlands)

Funder Name

Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON) (The Netherlands)

Funder Name

Roche Nederland B.V. (The Netherlands)

Funder Name

Amgen (The Netherlands)

Alternative Name(s)

Amgen Inc., Applied Molecular Genetics Inc.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

Novartis Pharma B.V. (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	15/08/2003		Yes	No