ISRCTN26340837 https://doi.org/10.1186/ISRCTN26340837

# 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

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|---|---|---|
| **Submission date**<br>20/12/2005 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>20/12/2005 | **Overall study status**<br>Completed | |
| **Last Edited**<br>09/11/2007 | **Condition category**<br>Cancer | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
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

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Non Hogdkin'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(s)
Complete Remission (CR) rate.

### Key secondary outcome(s))
1. Relapse rate
2. Event-free survival
3. Overall survival
4. Treatment-related morbidity
5. Therapy-related hospital admissions
6. Mortality

### 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

### Healthy volunteers allowed
No

### Age group
Senior

### Sex
All

### 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)

**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

**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 |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |