

# A randomised phase III study of chimeric anti-CD20 monoclonal antibody (rituximab) with two-weekly CHOP chemotherapy (CHOP 14) in elderly patients with intermediate or high-risk non-Hodgkins lymphoma

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<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/08/2021	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**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**  
Ho46; NL149 (NTR184)

# Study information

## Scientific Title

A randomised phase III study of chimeric anti-CD20 monoclonal antibody (rituximab) with two-weekly CHOP chemotherapy (CHOP 14) in elderly patients with intermediate or high-risk non-Hodgkins lymphoma

## Acronym

HOVON 46 NHL

## Study objectives

An evaluation of the effect of anti-CD20 (rituximab) combined with two-weekly cyclophosphamide, doxorubicin, vincristine and prednisone (CHOP) and Granulocyte Colony Stimulating Factor (G-CSF) in comparison to two-weekly CHOP and G-CSF alone.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the local medical ethics committee

## Study design

Randomised, active controlled, parallel group, multicentre trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Non Hodgkin's Lymphoma (NHL)

## Interventions

Patients will be randomised between:

Arm A: Eight cycles of CHOP every two weeks plus G-CSF (pegfilgrastim, Neulasta®) once per cycle

Arm B: Eight cycles of CHOP every two weeks plus G-CSF (pegfilgrastim, Neulasta®) once per cycle combined with six administrations of Rituximab (Mabthera®)

## Intervention Type

Drug

## Phase

Phase III

## Drug/device/biological/vaccine name(s)

Rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone and granulocyte colony stimulating factor.

**Primary outcome(s)**

1. Event-free survival (i.e. time from registration to induction failure (i.e. no Complete Response [CR] or Complete Response uncertain [CRu] on induction treatment), death or relapse whichever occurs first)
2. The time to failure of patients with induction failure is set at one day

**Key secondary outcome(s)**

1. Complete response
2. Overall survival measured from the time of registration
3. Disease-free interval (duration of the first CR) measured from the time of achievement of CR to day of relapse or death from any cause (whichever occurs first)
4. Toxicity

**Completion date**

01/10/2006

**Eligibility****Key inclusion criteria**

1. Patients with a confirmed histologic diagnosis of Non-Hodgkins Lymphoma (NHL) according to the World Health Organisation (WHO) classification:
  - a. Mantle Cell Lymphoma (MCL)
  - b. Follicular Lymphoma (grade III) (FL III)
  - c. Diffuse Large B-Cell Lymphoma (DLBCL)
2. Low-intermediate, high-intermediate or high risk NHL according to age-adjusted International Prognostic Index (IPI) score
3. NHL must be CD20 positive
4. Age 65 years or more
5. WHO performance status zero to two
6. Written informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**Key exclusion criteria**

1. Intolerance of exogenous protein administration
2. Severe cardiac dysfunction (New York Heart Association [NYHA] classification II to IV) or Left Ventricular Ejection Fraction (LVEF) less than 45%
3. Significant renal dysfunction (serum creatinine greater than or equal to 150 mmol/l), unless related to NHL
4. Significant hepatic dysfunction (total bilirubin greater than or equal to 30 mmol/l or

transaminases greater than or equal to 25 times normal level), unless related to NHL

5. Suspected or documented Central Nervous System involvement by NHL

6. Patients known to be Human Immunodeficiency Virus (HIV)-positive

7. Patients with active, uncontrolled infections

8. Patients with uncontrolled asthma or allergy, requiring steroid treatment

or treatment with chemotherapy, radiotherapy or immunotherapy for this lymphoma, except local radiotherapy in case of (potential) organ dysfunction by localised lymphoma mass or infiltration

9. Story of active cancer during the past five years, except basal carcinoma of the skin or stage zero cervical carcinoma

**Date of first enrolment**

28/11/2001

**Date of final enrolment**

01/10/2006

## **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/056kpx27>

## **Funder(s)**

**Funder type**

Research organisation

## Funder Name

Dutch Haemato-Oncology Association (Stichting Hemato-Oncologie Volwassenen Nederland) (HOVON) (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?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes