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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

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 20/12/2005	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 20/08/2021	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

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
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

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 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 measure
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

Secondary outcome measures
1. Complete response
2. Overall survival measured form 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

Overall study start date
28/11/2001

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
400

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)

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Vrije University Medical Centre (VUMC)
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Sponsor type
Research organisation

Website
http://www.hovon.nl/

ROR
https://ror.org/056kpdx27

Funder(s)

Funder type
Research organisation

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