

A randomised phase III study on the effect of the chimeric anti-CD20 monoclonal antibody (MabThera®) during sequential chemotherapy followed by autologous stem cell transplantation in patients with relapsed or progressive B-cell 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 28/01/2019	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00012051

Protocol serial number

NTR188; Ho44

Study information

Scientific Title

Rituximab improves the treatment results of DHAP-VIM-DHAP and ASCT in relapsed/progressive aggressive CD20+ NHL: a prospective randomized HOVON trial.

Acronym

HOVON 44 NHL

Study objectives

Evaluation of the effect of MabThera® with respect to response to reinduction treatment before autologous stem cell transplantation and overall survival and event free survival after autologous stem cell transplantation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Primary study design

Interventional

Study design

Multicentre randomised active controlled parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Non-Hodgkin's lymphoma (NHL)

Interventions

Patients will be randomised to:

Arm A:

Cycle I: DHAP

Cycle II: VIM, in case of partial remission (PR) or complete remission (CR)

Cycle III: DHAP or VIM, BEAM + autologous SCT

Arm B:

Cycle I: DHAP + rituximab

Cycle II: VIM + rituximab, in case of PR or CR

Cycle III: DHAP or VIM + rituximab, BEAM + autologous SCT

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

MabThera®, rituximab; dexamethasone, cytarabine, cisplatin (DHAP); carmustine, etoposide, cytarabine, melphalan (BEAM); etoposide, ifosfamide, mitoxantrone, prednisone (VIM)

Primary outcome(s)

Overall survival measured from the date of registration. Patients still alive or lost to follow up are censored at the last day they were known to be alive.

Key secondary outcome(s)

1. Response to DHAP-VIM with or without rituximab (MabThera®)
2. Event-free survival (i.e. time from registration to the date of stable disease after both the first and second reinduction cycle, documented progression, relapse or death, whichever comes first)

Completion date

01/01/2007

Eligibility**Key inclusion criteria**

1. Malignant lymphoma based upon a representative histology specimen according to the REAL classification at relapse or progression:
 - 1.1. Follicular center lymphoma, follicular (grade III)
 - 1.2. Diffuse large B-cell lymphoma
 - 1.3. Primary mediastinal B-cell lymphoma
2. CD20 positive
3. First progression or relapse during/after adriamycin containing regimen. 'Progressive' includes patients who have progressive disease (PD, without prior response) and patients who have progression after first PR
4. Aged 18 - 65 years inclusive
5. World Health Organization (WHO) performance status 0 - 1
6. Witnessed written informed consent according to the center requirements

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Patients with history of intolerance of exogenous protein administration
2. Patients with severe cardiac dysfunction (New York Heart Association [NYHA] classification II - IV)
3. Patients with severe pulmonary dysfunction (vital capacity or diffusion capacity less than 70% of predicted value) unless clearly related to non-Hodgkins Lymphoma (NHL) involvement
4. Patients with hepatic dysfunction, bilirubin or transaminase greater than or equal to 25 x upper normal limit
5. Patients with renal dysfunction (serum creatinine greater than or equal to 180 mmol/l or clearance less than or equal to 40 ml/min)
6. Prior treatment with immunotherapy or radiation therapy within the last month before entering the study
7. Patients with active uncontrolled infections
8. Patients known to be human immunodeficiency virus (HIV)-positive
9. Patients with NHL localisation in the central nervous system
10. Patients with (EBV) post-transplant lymphoproliferative disorder

Date of first enrolment

20/11/2000

Date of final enrolment

01/01/2007

Locations**Countries of recruitment**

Netherlands

Study participating centre

University Medical Center Groningen

Groningen

Netherlands

9700 RB

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

Koningin Wilhelmina Fonds (KWF) (Netherlands)

Funder Name

Dutch Haemato-Oncology Association (Stichting Hemato-Oncologie Volwassenen Nederland) (HOVON) (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	15/01/2008	28/01/2019	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes