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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 28/01/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.hovon.nl

Contact information

Type(s)
Scientific

Contact name
Prof E. Vellenga

Contact details
University Medical Center Groningen
Department of Hematology
P.O. Box 30001
Groningen
Netherlands
9700 RB
+31 (0)50 361 2354
e.vellenga@int.umcg.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00012051

Secondary identifying numbers
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

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 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 measure
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.

Secondary outcome measures
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)

Overall study start date
20/11/2000

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

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)

Sponsor details
Vrije University Medical Centre (VUMC)
PO Box 7057
Amsterdam
Netherlands
1007 MB
+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
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

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	15/01/2008	28/01/2019	Yes	No