

Alemtuzumab, MabCampath® with 2-weekly CHOP chemotherapy for mature T-cell non-Hodgkin's lymphoma

Submission date 18/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 05/07/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 05/07/2010	Condition category 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

Contact name
Prof J.C. Nelemans

Contact details
University Medical Center Groningen (UMCG)
Afd. Hematologie
Postbus 30001
Groningen
Netherlands
9700 RB
+31 (0)50 361 2354
j.c.kluin@int.umcg.nl

Additional identifiers

Protocol serial number
HO69

Study information

Scientific Title

A phase II study of anti-CD52 monoclonal antibody (Alemtuzumab, MabCampath®) with 2-weekly CHOP chemotherapy (Camp-CHOP 14) in patients with mature T-cell non-Hodgkin's lymphoma

Acronym

HOVON 69 T-NHL

Study objectives

Evaluation of the efficacy and toxicity of anti-CD52 (Alemtuzumab, MabCampath®) combined with 2-weekly cyclophosphamide, hydroxydaunorubicin (doxorubicin), Oncovin (vincristine), and prednisone/prednisolone (CHOP) and granulocyte colony-stimulating factor (G-CSF).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical Ethics Committee of the University Medical Center Groningen approved on the 11th August 2005 (ref: 2005.101)

Study design

Multicentre prospective non-randomised non-blinded active controlled interventional phase II study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mature T-cell non-Hodgkin's lymphoma

Interventions

Patients with T-NHL meeting all eligibility criteria will be registered and treated with: 8 cycles of CHOP every 2 weeks plus G-CSF (Pegfilgrastim), combined with 24 administrations of Alemtuzumab (MabCampath®).

Patients will be evaluated for response after 3 cycles of Camp-CHOP (all patients) and after 8 cycles of Camp-CHOP (if applicable, otherwise after last cycle administered). All patients, who have not attained at least a partial response (PR) after 3 cycles of Camp-CHOP, will go off protocol treatment.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Cyclophosphamide, hydroxydaunorubicin (doxorubicin), oncovin (vincristine), prednisone /prednisolone, granulocyte colony-stimulating factor

Primary outcome(s)

Complete response (CR) including complete response uncertain (CRu) on protocol

Key secondary outcome(s)

1. Event-free survival, i.e., time from registration to induction failure (no CR, CRu or PR on induction treatment), death or relapse whichever occurs first; the time to failure of patients with induction failure is set at one day
2. Overall survival measured from the time of registration
3. Disease-free interval (duration of the first CR/CRu) measured from the time of achievement of CR to day of relapse or death from any cause (whichever occurs first)
4. Toxicity, Common Terminology Criteria for Adverse Events (CTCAE) grade 3 - 4, except nausea, vomiting, alopecia and haematological toxicity

Completion date

01/11/2007

Eligibility**Key inclusion criteria**

1. Patients with a confirmed histologic diagnosis of T-cell non-Hodgkin's lymphoma (T-NHL) according to the World Health Organization (WHO) classification:
 - 1.1. Extranodal NK/T cell lymphoma, nasal type
 - 1.2. Enteropathy-type T-cell lymphoma (EATL), if measurable disease
 - 1.3. Subcutaneous panniculitis-like T-NHL
 - 1.4. Angioimmunoblastic T-cell lymphoma
 - 1.5. Peripheral T-cell lymphoma, unspecified (T-NHL NOS)
2. Aged 18 - 65 years inclusive, either sex
3. Stage II or more
4. WHO performance status 0, 1 or 2
5. Measurable disease
6. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Patients with NK/T-NHL of the following type:
 - 1.1. Precursor T cell lymphoblastic lymphoma/leukaemia
 - 1.2. All mature T cell leukaemias (T-PLL, ATLL, NK cell leukaemia, T-LGL)
 - 1.3. Anaplastic large cell lymphoma
 - 1.4. Hepatosplenic T cell lymphoma
 - 1.5. Enteropathy-type T cell lymphoma without measurable disease
 - 1.6. Blastic NK cell lymphoma
2. Intolerance of exogenous protein administration
3. Severe cardiac dysfunction (New York Heart Association [NYHA] classification II - IV, appendix F) or left ventricular ejection fraction (LVEF) less than 45%
4. Significant renal dysfunction (serum creatinine greater than or equal to 150 µmol/l), unless related to NHL
5. Significant hepatic dysfunction (total bilirubin greater than or equal to 30 µmol/l or transaminases greater than or equal to 2.5 times normal level), unless related to NHL
6. Suspected or documented central nervous system involvement by NHL
7. Patients known to be human immunodeficiency virus (HIV)-positive
8. Patients with active, uncontrolled infections
9. Patients with uncontrolled asthma or allergy, requiring steroid treatment
10. Prior treatment with chemotherapy, radiotherapy or immunotherapy for this lymphoma, except local radiotherapy in case of (potential) organ dysfunction by localised lymphoma mass or infiltration
11. History of active cancer during the past 5 years, except basal carcinoma of the skin or stage 0 cervical carcinoma

Date of first enrolment

16/11/2005

Date of final enrolment

01/11/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Center Groningen (UMCG)

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

Dutch Haemato-Oncology Association (Stichting Hemato-Oncologie Volwassenen Nederland) (HOVON) (Netherlands) (ref: HO69)

Funder Name

The National Cancer Fund (Koningin Wilhelmina Fonds [KWF]) (Netherlands) (ref: 2005-12)

Funder Name

Bayer Schering Pharma (MabCampath) (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?
Study website	Study website	11/11/2025	11/11/2025	No	Yes