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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 05/07/2010	**Overall study status** Completed	
Last Edited 05/07/2010	**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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
16/11/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

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)

Sponsor details
HOVON Data Center
Erasmus MC - Daniel den Hoed
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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) (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

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