

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

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

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## 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/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

### 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?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes