

# Alemtuzumab as remission induction for adult patients with acute lymphoblastic leukemia in relapse: a randomized phase II study

<b>Submission date</b> 07/06/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 07/06/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 07/06/2006	<b>Condition category</b> 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

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## Additional identifiers

**Protocol serial number**  
HO74

## Study information

**Scientific Title**

**Acronym**

HOVON 74 ALL

**Study objectives**

The hypothesis to be tested is that arm A and/or arm B are feasible.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Primary study design**

Interventional

**Study design**

Randomized, phase II study

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Acute lymphoblastic leukemia (ALL)

**Interventions**

Relapsed ALL patients under the age of 71 years will be registered and randomized to receive:  
Arm A: prednisone and methotrexate in the pre-phase and thereafter two remission induction courses of alemtuzumab 30 mg

Arm B: prednisone and methotrexate in the pre-phase and thereafter two remission induction courses of alemtuzumab 60 mg

**Intervention Type**

Drug

**Phase**

Phase II

**Drug/device/biological/vaccine name(s)**

Alemtuzumab, prednisone and methotrexate

**Primary outcome(s)**

1. Percentage of patients that reach a complete remission (CR) on induction cycle I in each arm
2. Percentage of patients with severe toxicity on induction cycle I in each arm

**Key secondary outcome(s)**

1. Toxicity profile related to each treatment step and intervals between treatment steps
2. Event-free survival (i.e. time from registration until no CR on protocol, relapse or death,

- whichever comes first). Event-free survival for patients without a CR is set at one day.
3. Disease-free survival (i.e. time from achievement of CR to date of relapse or death from any cause, whichever occurs first)
  4. Overall survival measured from time of registration

**Completion date**

15/04/2008

## Eligibility

**Key inclusion criteria**

1. Age 18 - 70 years inclusive
2. First or second relapse of precursor B-cell ALL (B-ALL) or T-cell (T-ALL) (including Philadelphia chromosome or BCR-ABL tyrosine kinase positive ALL)
3. Duration of last complete remission at least 6 months
4. World Health Organization (WHO) performance status 0, 1, or 2
5. Negative pregnancy test at inclusion if applicable
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. Mature B-cell ALL, i.e. Burkitt leukemia/lymphoma
2. Acute undifferentiated leukemia (AUL)
3. Treatment with alemtuzumab at any time prior to registration
4. Intolerance of exogenous protein administration
5. Central nervous system (CNS) leukemia
6. Severe cardiovascular disease (arrhythmias requiring chronic treatment, congestive heart failure or symptomatic ischemic heart disease)
7. Severe pulmonary dysfunction (Common Terminology Criteria for Adverse Events [CTCAE] grade III-IV)
8. Severe neurological or psychiatric disease
9. Significant hepatic dysfunction (serum bilirubin or transaminases  $\geq$  3 times normal level)
10. Significant renal dysfunction (serum creatinine  $\geq$  3 times normal level)
11. Patients with active, uncontrolled infections
12. Patients with uncontrolled asthma or allergy, requiring oral steroid treatment at the time of registration

- 13. Patients known to be human immunodeficiency virus (HIV)-positive
- 14. Patient is a lactating woman
- 15. Any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule

**Date of first enrolment**

15/05/2006

**Date of final enrolment**

15/04/2008

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**Leiden University Medical Center (LUMC)**

Leiden

Netherlands

2300 RC

## **Sponsor information**

**Organisation**

Dutch Haemato-oncology Association (Stichting Hemato-Oncologie Volwassenen Nederland) (HOVON)

**ROR**

<https://ror.org/056kpx27>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Dutch Cancer Society

**Funder Name**

Johnson and Johnson-Orthobiotech

**Funder Name**

Schering International

**Funder Name**

Novartis Pharma B.V.

**Funder Name**

Amgen

**Alternative Name(s)**

Amgen Inc., Applied Molecular Genetics Inc.

**Funding Body Type**

Government organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

United States of America

**Funder Name**

Roche Nederland BV

## 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="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes