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

Submission date 07/06/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/06/2006	**Overall study status** Completed	
Last Edited 07/06/2006	**Condition category** Cancer	

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 >/= 3 times normal level)
10. Significant renal dysfunction (serum creatinine >/= 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/056kpdx27

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?
Study website	Study website	11/11/2025	11/11/2025	No	Yes