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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
Registration date 07/06/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 07/06/2006	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

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
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

Study design
Randomized, phase II study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
15/05/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

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)

Sponsor details
HOVON Data Center
Erasmus Medical Center
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Sponsor type
Research organisation

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

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