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Feasibility study using repeated intensive chemotherapy courses for patients with primary acute lymphoblastic leukemia in adults age 18 - 39 years inclusive

Submission date 20/08/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 06/09/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 07/09/2011	**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
Ho70

Study information

Scientific Title
Feasibility study using repeated intensive chemotherapy courses for patients with primary acute lymphoblastic leukemia in adults age 18 - 39 years inclusive: A phase II multicentre study

Acronym
HOVON 70 ALL

Study objectives
The hypothesis to be tested is that treatment with 1 prephase course, 2 induction courses, 1 consolidation course, allo-SCT or maintenance treatment is feasible, and efficacy meets the expectations as described in the protocol.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Ethics Committee (MEC) of University Medical Centre Groningen approved on the 15th of August 2005 (ref: METc 2005/062)

Study design
Prospective phase II multicentre non-randomised trial

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 contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Acute Lymphoblastic Leukemia (ALL)

Interventions

Patients will be treated with the following courses:
1. Pre-phase course consisting of 60 mg/m2/day for 7 days. Induction consisting of prednisone, vincristine, daunorubicin, cyclophosphamide and L-asparaginase
2. Consolidation A consisting of 6-thioguanine, cyclophosphamide and Ara-C. Consolidation B consisting of prednisone, vincristine, 6-mercaptopurine and MTX
3. Intensification IA consisting of dexamethasone, vindesine, adriamycine and L-asparaginase
4. Intensification IB consisting of 6-thioguanine, etoposide and Ara-C
5. Interphase A and B consisting of prednisone, vincristing, 6-mercaptopurine and MTX
6. Intensification IIA consisting of prednisone, vincristine, daunorubicine and L-asparaginase
7. Intensification IIB consisting of 6-thioguanine, cyclophosphamide and Ara-C
8. Maintenance consisting of 6-mercaptopurine and MTX

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Percentage of patients that reach a complete response (CR), complete all intensive phases of the protocol, and start with maintenance therapy within 11 months after start pre-phase or receive an allogeneic stem cell transplantation within 7.5 months after start pre-phase.

Secondary outcome measures
1. CR rate after remission induction, consolidation, intensification, and maintenance
2. Toxicity profile related to each treatment step and intervals between treatment steps
3. 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
4. Disease-free survival (i.e. time from achievement of CR to day of relapse or death from any cause, whichever occurs first)
5. Overall survival measured from time of registration

Overall study start date
21/10/2005

Completion date
01/09/2012

Eligibility

Key inclusion criteria
1. Age 18 - 39 years inclusive
2. Primary previously untreated ALL (including Philadelphia chromosome or BCR-ABL positive ALL)
3. WHO performance status 0, 1, or 2
4. Negative pregnancy test at inclusion if applicable
5. Written informed consent

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Mature B-cell ALL
2. Acute undifferentiated leukemia
3. Severe cardiovascular disease (arrhythmias requiring chronic treatment, congestive heart failure or symptomatic ischemic heart disease)
4. Severe pulmonary dysfunction (CTCAE grade III-IV)
5. Severe neurological or psychiatric disease
6. Significant hepatic dysfunction (serum bilirubin or transaminases ≥ 3 times normal level)
7. Significant renal dysfunction (serum creatinine ≥ 3 times normal level)
8. History of active malignancy during the past 5 years with the exception of basal carcinoma of the skin or stage 0 cervical carcinoma
9. Active, uncontrolled infections
10. Patient known to be HIV-positive
11. Patient is a lactating woman
12. Any psychological, familial, sociological and geographical condition potentially hampering compliance with the study protocol and follow-up schedule

Date of first enrolment
21/10/2005

Date of final enrolment
01/09/2012

Locations

Countries of recruitment
Belgium

Netherlands

Study participating centre
Dept. of Hematology
Rotterdam
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Sponsor information

Organisation
Dutch Haemato-Oncology Association (Stichting Hemato-Oncologie Volwassenen Nederland) (HOVON) (Netherlands)

Sponsor details
P/a HOVON Data Center
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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)

Funder Name
Dutch Cancer Fund (KWF) (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