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Early intensification by (un)-related allogeneic or autologous stem cell transplantation in adult Acute Lymphoblastic Leukaemia: a phase II study

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
26/08/2021

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HO37, NL191 (NTR228)

Study information

Scientific Title
Early intensification by (un)-related allogeneic or autologous stem cell transplantation in adult Acute Lymphoblastic Leukaemia: a phase II study

Acronym
HOVON 37 ALL

Study objectives
Patients who are in first Complete Response (CR) after autologous transplantation, may be randomised between no further treatment (arm A) and maintenance chemotherapy (arm B). The hypothesis to be tested is that maintenance therapy will prolong disease free survival, calculated from the date of randomisation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, active controlled, parallel group, multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
All patients will receive early intensification:
Cycle 1: prednisone, vincristine, daunorubicin, aspariganse, MTX i.t.

Cycle 2: Cytarabine, Mitoxantrone, MTX i.t.
Cycle 3: Methotrexate, asparaginase, 6-MP, MTX i.t.

After intensification patients will receive either an allogeneic sibling stem cell transplantation, a matched unrelated donor stem cell transplantation or an autologous stem cell transplantation.

Patients who received an autologous stem cell transplantation will be randomised between:
Arm A: no further treatment.
Arm B: maintenance treatment with 6-MP and MTX.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Prednisone, vincristine, daunorubicin, aspariganse, methotrexate (MTX), cytarabine, mitoxantrone, mercaptopurine (6-MP)

Primary outcome measure
Response after each course of chemotherapy and date of CR.

Secondary outcome measures
1. Disease-free survival (i.e. time from achievement of first CR to the date of relapse or death from any cause, whichever occurs first)
2. Event-free survival (i.e. time from start of therapy to the date of no complete response, death or relapse whichever occurs first): this takes into consideration induction failures and toxic deaths. The time to failure of patients with induction failure is set at one day
3. Overall survival will be measured from time of registration until death or last contact
4. Toxicities and treatment related mortality

Overall study start date
01/04/1999

Completion date
01/11/2005

Eligibility

Key inclusion criteria
1. Age between 16 and 59 (inclusive) years
2. Previously untreated with chemotherapy
3. Acute Lymphoblastic Leukaemia (ALL) according to the French-American-British (FAB) criteria and immunological marker analysis (B-precursor ALL, T-cell Acute Lymphoblastic Leukaemia [T-ALL] and Acute Undifferentiated Leukaemia [AUL])
4. World Health Organisation (WHO) performance status grade zero, one, two or three
5. Patient gives informed consent

Participant type(s)

Patient

Age group
Adult

Sex
Not Specified

Target number of participants
200

Key exclusion criteria
1. B-ALL (= mature B-ALL)
2. Severe cardiac, pulmonary, hepatic, renal, neurologic, psychiatric or metabolic disease
3. Second malignant disease, except cervix carcinoma stage I and non-melanoma skin cancer
4. Persisting renal insufficiency, creatinine more than 200 mmol/l
5. Active uncontrolled infections
6. Human Immunodeficiency Virus (HIV) positivity on serological tests

Date of first enrolment
01/04/1999

Date of final enrolment
01/11/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Utrecht,
Utrecht
Netherlands
3508 GA

Sponsor information

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

Sponsor details
Vrije University Medical Centre (VUMC)
PO Box 7057

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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
Koningin Wilhelmina Fonds (KWF) (The Netherlands)

Funder Name
Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON) (The 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/06/2011	26/08/2021	Yes	No
Results article		23/02/2021	26/08/2021	Yes	No