Early intensification by (un)related allogeneic or autologous stem cell transplantation in adult acute lymphoblastic leukemia. A phase II study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20150

Source
NTR

Brief title
HOVON 37 ALL

Health condition

Acute Lymphoblastic Leukemia (ALL).

Sponsors and support

Primary sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
P/a HOVON Data Center
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Source(s) of monetary or material Support: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
Koningin Wilhelmina Fonds (KWF)

Intervention

Outcome measures

Primary outcome

Response after each course of chemotherapy and date of CR.

Secondary outcome

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.

Study description

Background summary

Study phase:

phase 2.

Study objectives:

1. To study prospectively the value of early intensification by allogeneic or autologous stem cell transplantation in ALL;

2. To study prospectively stem cell transplantation with a matched unrelated donor in high-risk ALL when no sibling donor is available;

3. To study the value of donor lymphocyte infusion (DLI) in high-risk ALL with a molecular or cytogenetic relapse after allogeneic stem cell transplantation or in high-risk ALL with persistent residual disease (molecular; cytogenetic);

4. To study the value of maintenance chemotherapy in ALL patients after autologous transplantation;

5. To study leukemic cell reduction by means of (semi-quantitative) molecular techniques during induction chemotherapy, after consolidation with stem cell transplantation, and during maintenance chemotherapy in patients receiving an autologous stem cell transplantation.

Patient population:

Patients with previously untreated, B-precursor ALL, T-ALL or AUL, age 16-59 years inclusive.

Study design:

Prospective, multicenter, randomized.

Study objective

Patients who are in 1st CR after autologous transplantation, may be randomized 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 randomization.

Study design

N/A

Intervention

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 randomized between:

- Arm A: no further treatment.

- Arm B: maintenance treatment with 6-MP and MTX.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age between 16 and 59 (inclusive) years;

2. Previously untreated with chemotherapy;

3. ALL according to the FAB criteria and immunological marker analysis (B-precursor ALL, T-ALL and AUL);

4. WHO performance status grade 0, 1, 2 or 3;

5. Patient informed consent.

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. HIV positivity on serological tests.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-1999
Enrollment:	200
Type:	Actual

Ethics review

Positive opinion

Date:	06-09-2005

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL191
NTR-old	NTR228
Other	: HO37
ISRCTN	ISRCTN77441569

Study results

Summary results
N/A