INTERFANT-06.
International collaborative treatment protocol for infants under one year of age
with acute lymphoblastic or biphenotypic leukemia.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20078

Source
NTR

Brief title
Interfant-06.

Sponsors and support

Primary sponsor: the different international study groups
Source(s) of monetary or material Support: no

Intervention

Outcome measures

Primary outcome

Event free survival.

Secondary outcome

Survival.

Study description

Background summary

Infant acute lymphoblastic leukemia (ALL) has a poor prognosis compared to ALL in older children. Becuase it is a rare disease, in 1999 an international collaboration was started to try to improve outcome for infant ALL. Interfant-99 was the first study leading to an event-free survival of 47%. Early bone marrow relapses were the major reason for therapy failure. The interfant-06 study aims to improve therapy by comparing two different early therapy intensifications: two "AML" induction blocks versus protocol Ib given directly after induction therapy in patients with a MLL gene rearrangement. Other aims are:
- to assess the outcome of the Interfant-06 protocol compared to the historical control series, especially the Interfant-99.
- To study which factors have independent prognostic value.
- To assess the role of SCT in patients at high risk for relapse.

Study objective

The primary aim of the study is:
1. To assess the role of an early intensification of two "AML" induction blocks versus protocol Ib directly after induction, in a randomized way in MR and HR patients.
Secondary aims are:
2. To assess the role of an early intensification of two "AML" induction blocks versus protocol Ib directly after induction, in a randomized way in MR and HR patients, separately.
3. To assess the overall outcome of the Interfant-06 protocol compared to the historical control series, especially the Interfant-99.
4. To assess the outcome of LR, MR and HR patients as compared to the historical control series in Interfant-99.
5. To study which factors have independent prognostic value.
6. To assess the role of SCT in HR patients.

Intervention

Comparison of early intensification of two "AML" induction blocks versus protocol Ib directly after induction, in a randomized way in medium risk and high risk patients.

Contacts

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Eligibility criteria

Inclusion criteria

1. Children aged 365 days or less with newly diagnosed acute lymphoblastic leukemia (ALL) or biphenotypic leukemia according to EGIL criteria. Children with CNS or testicular leukemia at diagnosis are eligible;
2. Morphological verification of the diagnosis, confirmed with cytochemistry and immunophenotyping. In case a bone marrow aspiration results in a “dry tap”, a trephine biopsy is advised unless it is possible to confirm the diagnosis by peripheral blood examination;
3. Informed consent of the parents or other legally authorized guardian of the patient.

Exclusion criteria

1. Mature B-ALL, defined by the immunophenotypical presence of surface immunoglobulines or t(8;14) and breakpoint as in B-ALL;
2. The presence of the t(9;22) (q34;q11) or bcr-abl fusion in the leukemic cells (if these data are not known, the patient is eligible);
3. Age > 365 days;
4. Relapsed ALL;

5. Systemic use of corticosteroids less than 4 weeks before diagnosis. Patients who received corticosteroids by aerosol are eligible for the study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2006
Enrollment:	445
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-05-2006
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	NL635
NTR-old	NTR695
Other	: N/A
ISRCTN	ISRCTN12500962

Study results

Summary results
N/A