

International collaborative treatment protocol for infants under age one with acute lymphoblastic or biphenotypic leukemia

Submission date 21/07/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/07/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 14/07/2014	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

<http://www.cancerhelp.org.uk/trials/a-trial-looking-at-treatment-for-babies-with-acute-lymphoblastic-leukaemia-or-mixed-type-leukaemia>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Study information

Scientific Title

Acronym

Interfant-06

Study objectives

The primary aim of the study is:

1. To assess the role of an early intensification of two acute myeloid leukaemia (AML)-induction blocks versus protocol Ib directly after induction, in a randomized way in medium-risk (MR) and high-risk (HR) patients

Secondary aims are:

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, separately
2. To assess the overall outcome of the Interfant-06 protocol compared to the historical control series, especially the Interfant-99 (ISRCTN24251487)
3. To assess the outcome of low-risk (LR), MR and HR patients as compared to the historical control series in Interfant-99
4. To study which factors have independent prognostic value
5. To assess the role of stem cell transplantation (SCT) in HR patient

As of 24/02/2011 the anticipated end date for this trial has been extended from 01/01/2012 to 19/05/2013.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Biphenotypic leukemia, acute lymphoblastic leukemia (ALL)

Interventions

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

Intervention Type

Other

Phase

Phase III

Primary outcome(s)

Event-free survival

Key secondary outcome(s)

Survival

Completion date

19/05/2013

Eligibility

Key inclusion criteria

1. Children aged 365 days or less with newly diagnosed acute lymphoblastic leukemia (ALL) or biphenotypic leukemia according to European Group for the Immunological Classification of Leukemia (EGIL) criteria. Children with central nervous system (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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Upper age limit

1 years

Sex

All

Key exclusion criteria

1. Mature B-cell acute lymphoblastic leukemia (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 this data is not known, the patient is eligible)
3. Age >365 days
4. Relapsed ALL
5. Systemic use of corticosteroids less than four weeks before diagnosis. Patients who have received corticosteroids by aerosol are eligible for the study

Date of first enrolment

01/01/2006

Date of final enrolment

19/05/2013

Locations

Countries of recruitment

Netherlands

United States of America

Study participating centre

Erasmus Medical Center

Rotterdam

Netherlands

3015 GJ

Sponsor information

Organisation

Stichting Kinder Oncologie (SKION) (The Netherlands)

ROR

<https://ror.org/01zs6bp63>

Funder(s)

Funder type

University/education

Funder Name

Erasmus Medical Center (Netherlands)

Alternative Name(s)

Erasmus Medical Center, Erasmus MC, Erasmus Universitair Medisch Centrum, Erasmus University Medical Center, Universitair Medisch Centrum Rotterdam, Erasmus Universitair Medisch Centrum Rotterdam, EMC

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration