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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	[_] Prospectively registered [_] Protocol
Registration date 21/07/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 14/07/2014	**Condition category** Cancer	[_] Individual participant data [_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Event-free survival

Secondary outcome measures
Survival

Overall study start date
01/01/2006

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

Age group
Child

Upper age limit
1 Years

Sex

Both

Target number of participants
445

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
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Sponsor information

Organisation
Stichting Kinder Oncologie (SKION) (The Netherlands)

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Sponsor type
Hospital/treatment centre

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

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