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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 21/07/2006	**Overall study status** Completed	
Last Edited 14/07/2014	**Condition category** Cancer	

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
Prof Rob Pieters

Contact details
Erasmus Medical Center
Sophia Children's Hospital
Department of Oncology/Hematology
PO Box 2060
Rotterdam
Netherlands
3015 GJ
+31 (0)10 4636691
rob.pieters@erasmusmc.nl

Additional identifiers

Protocol serial number
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

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