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Interfant 99: International collaborative treatment protocol for infants under one year with acute lymphoblastic leukaemia

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 18/11/2009	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00015873

Protocol serial number
NTR182

Study information

Scientific Title

Acronym
Interfant 99

Study objectives
A late intensification course (VIMARAM) improves the outcome of infants with acute lymphoblastic leukaemia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added as of 24/07/2007: Approval was given before recruitment.

Study design
Multicentre randomised active controlled parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute lymphoblastic leukaemia (ALL)

Interventions
Interventions amended as of 24/07/2007:
Intensification course VIMARAM (a course that includes high-dose cytarabine and methotrexate)

Interventions provided at time of registration:
Intensification course VIMARAM

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Event free survival

Key secondary outcome(s))
Added as of 24/07/2007: Survival

Completion date

01/01/2006

Eligibility

Key inclusion criteria
1. Aged less than 366 days
2. Acute lymphoblastic leukaemia

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
366 days

Sex
All

Key exclusion criteria
Prior therapy for leukaemia (except emergency treatment).

Date of first enrolment
01/01/1999

Date of final enrolment
01/01/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus MC-Sophia Childrens Hospital
Rotterdam
Netherlands
3015 GJ

Sponsor information

Organisation
Interfant Collaborative Group (Netherlands)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Added as of 24/07/2007: Participating hospitals covered the costs of this trial.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/07/2007		Yes	No
Results article	results	29/10/2009		Yes	No