

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
Registration date 20/12/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 18/11/2009	Condition category Cancer	☐ Individual participant data

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.

Primary study design

Interventional

Study design

Multicentre randomised active controlled parallel group trial

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