

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/11/2009	Condition category Cancer	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00015873

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

Event free survival

Secondary outcome measures

Added as of 24/07/2007: Survival

Overall study start date

01/01/1999

Completion date

01/01/2006

Eligibility

Key inclusion criteria

1. Aged less than 366 days
2. Acute lymphoblastic leukaemia

Participant type(s)

Patient

Age group

Child

Upper age limit

366 Days

Sex

Both

Target number of participants

500

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)

Sponsor details

-
Rotterdam
Netherlands
-

Sponsor type
Not defined

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

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

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