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Comparison of Different Combination Chemotherapy Regimens in Treating Infants With Acute Lymphoblastic Leukemia

The recruitment status of this study is unknown because the information has not been verified recently.

Verified **October 2006** by National Cancer Institute (NCI). Recruitment status was Active, not recruiting

First Received on May 6, 2001. Last Updated on November 11, 2010 [History of Changes](#)

Sponsor:	Dutch Childhood Oncology Group
Information provided by:	National Cancer Institute (NCI)
ClinicalTrials.gov Identifier:	NCT00015873

▶ Purpose

RATIONALE: Drugs used in chemotherapy use different ways to stop cancer cells from dividing so they stop growing or die. Combining more than one drug may kill more cancer cells. It is not yet known which combination chemotherapy regimen is most effective for treating infants with acute lymphoblastic leukemia.

PURPOSE: Randomized phase III trial to compare the effectiveness of different combination chemotherapy regimens in treating infants who have newly diagnosed acute lymphoblastic leukemia.

Condition	Intervention	Phase
Leukemia	Drug: asparaginase Drug: busulfan Drug: cyclophosphamide Drug: cyclosporine Drug: cytarabine Drug: daunorubicin hydrochloride Drug: dexamethasone Drug: etoposide Drug: leucovorin calcium Drug: mercaptopurine Drug: methotrexate Drug: prednisolone Drug: prednisone Drug: thioguanine Drug: vincristine sulfate Procedure: allogeneic bone marrow transplantation	Phase III

Study Type: Interventional
 Study Design: Primary Purpose: Treatment

Official Title: International Collaborative Treatment Protocol for Infants Under One Year With Acute Lymphoblastic Leukemia

Resource links provided by NLM:

[MedlinePlus](#) related topics: [Bone Marrow Transplantation](#) [Cancer](#)
[Chronic Lymphocytic Leukemia](#) [Leukemia](#)

[Drug Information](#) available for: [Dexamethasone](#) [Cyclophosphamide](#) [Prednisolone](#) [6-Mercaptopurine](#) [Prednisolone acetate](#) [Prednisone](#) [Depo-medrol](#) [Busulfan](#) [Vincristine](#)
[Leucovorin](#) [Methotrexate](#) [Cytarabine hydrochloride](#) [Daunorubicin](#)
[Daunorubicin hydrochloride](#) [Etoposide](#) [Citrovorum factor](#) [Dexamethasone acetate](#)
[Cyclosporine](#) [Doxiproct plus](#) [Medrol veriderm](#) [Cyclosporin](#) [Methylprednisolone](#)

[Etoposide phosphate](#) [Prednisolone sodium phosphate](#) [Cytarabine](#) [Thioguanine](#)
[Leucovorin Calcium](#) [Prednisolone Sodium Succinate](#) [Dexamethasone Sodium Phosphate](#)
[Vincristine sulfate](#) [Methylprednisolone Sodium Succinate](#)
[Methylprednisolone hemisuccinate](#) [Folinic acid calcium salt pentahydrate](#) [Mercaptopurine](#)
[6-Methylprednisolone](#) [L-Asparaginase](#)

[U.S. FDA Resources](#)

Further study details as provided by National Cancer Institute (NCI):

Primary Outcome Measures:

- Event-free survival at 3-4 years after diagnosis [Designated as safety issue: No]

Estimated Enrollment: 350
Study Start Date: May 1999

 [Show Detailed Description](#)

 **Eligibility**

Ages Eligible for Study: up to 1 Year
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

DISEASE CHARACTERISTICS:

- Diagnosis of acute lymphoblastic leukemia (ALL)
 - Newly diagnosed
 - Morphological verification by cytochemistry and immunophenotyping
- CNS or testicular leukemia at diagnosis allowed
- Trisomy 21 allowed

PATIENT CHARACTERISTICS:

Age:

- 365 days or less

Performance status:

- Not specified

Life expectancy:

- Not specified

Hematopoietic:

- Not specified

Hepatic:

- Not specified

Renal:

- Not specified

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- Not specified

Chemotherapy:

- No prior chemotherapy for leukemia

Endocrine therapy:

- At least 4 weeks since prior systemic corticosteroids
- Prior inhaled steroids allowed

Radiotherapy:

- No prior radiotherapy for leukemia

Surgery:

- Not specified

▶ Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00015873

[+](#) **Show 33 Study Locations**

Sponsors and Collaborators

Dutch Childhood Oncology Group

Investigators

Study Chair: Rob Pieters, MD, MSC, PhD Erasmus MC - Sophia Children's Hospital

▶ More Information

Additional Information:

[Clinical trial summary from the National Cancer Institute's PDQ® database](#) [EXIT](#)

Publications:

[Hempel G, Relling MV, de Rossi G, Stary J, De Lorenzo P, Valsecchi MG, Barisone E, Boos J, Pieters R. Pharmacokinetics of daunorubicin and daunorubicinol in infants with leukemia treated in the interfant 99 protocol. *Pediatr Blood Cancer*. 2010 Mar;54\(3\):355-60.](#)

[Mann G, Attarbaschi A, Schrappe M, De Lorenzo P, Peters C, Hann I, De Rossi G, Felice M, Lausen B, Leblanc T, Szczepanski T, Ferster A, Janka-Schaub G, Rubnitz J, Silverman LB, Stary J, Campbell M, Li CK, Suppiah R, Biondi A, Vora A, Valsecchi MG, Pieters R; Interfant-99 Study Group. Improved outcome with hematopoietic stem cell transplantation in a poor prognostic subgroup of infants with mixed-lineage-leukemia \(MLL\)-rearranged acute lymphoblastic leukemia: results from the Interfant-99 Study. *Blood*. 2010 Oct 14;116\(15\):2644-50. Epub 2010 Jun 30.](#)

[Lönnerholm G, Valsecchi MG, De Lorenzo P, Schrappe M, Hovi L, Campbell M, Mann G, Janka-Schaub G, Li CK, Stary J, Hann I, Pieters R; Interfant-99 study group. Pharmacokinetics of high-dose methotrexate in infants treated for acute lymphoblastic leukemia. *Pediatr Blood Cancer*. 2009 May;52\(5\):596-601.](#)

[van der Linden MH, Valsecchi MG, De Lorenzo P, Mörücke A, Janka G, Leblanc TM, Felice M, Biondi A, Campbell M, Hann I, Rubnitz JE, Stary J, Szczepanski T, Vora A, Ferster A, Hovi L, Silverman LB, Pieters R. Outcome of congenital acute lymphoblastic leukemia treated on the Interfant-99 protocol. *Blood*. 2009 Oct 29;114\(18\):3764-8. Epub 2009 Aug 5.](#)

[Van der Velden VH, Corral L, Valsecchi MG, Jansen MW, De Lorenzo P, Cazzaniga G, Panzer-Grümayer ER, Schrappe M, Schrauder A, Meyer C, Marschalek R, Nigro LL, Metzler M, Basso G, Mann G, Den Boer ML, Biondi A, Pieters R, Van Dongen JJ; Interfant-99 Study Group. Prognostic significance of minimal residual disease in infants with acute lymphoblastic leukemia treated within the Interfant-99 protocol. *Leukemia*. 2009 Jun;23\(6\):1073-9. Epub 2009 Feb 12.](#)

[Pieters R, Schrappe M, De Lorenzo P, Hann I, De Rossi G, Felice M, Hovi L, LeBlanc T, Szczepanski T, Ferster A, Janka G, Rubnitz J, Silverman L, Stary J, Campbell M, Li CK, Mann G, Suppiah R, Biondi A, Vora A, Valsecchi MG. A treatment protocol for infants younger than 1 year with acute lymphoblastic leukaemia \(Interfant-99\): an observational study and a multicentre randomised trial. *Lancet*. 2007 Jul 21;370\(9583\):240-50.](#)

Pieters R, Schrappe M, de Lorenzo P, et al.: Outcome of infants less than one year of age with acute lymphoblastic leukemia treated with the Interfant-99 protocol. [Abstract] *Blood* 108 (11): A-145, 2006.

ClinicalTrials.gov Identifier: [NCT00015873](#) [History of Changes](#)

Other Study ID Numbers: CDR0000068529, ICU-INTERFANT99, UKCCSG-LK-1999-05, EU-20063, EU-20588

Study First Received: May 6, 2001

Last Updated: November 11, 2010

Health Authority: United States: Federal Government

Keywords provided by National Cancer Institute (NCI):
untreated childhood acute lymphoblastic leukemia

Additional relevant MeSH terms:

Leukemia	Cyclosporins
Leukemia, Lymphoid	Cyclosporine
Precursor Cell Lymphoblastic Leukemia-	Asparaginase

Lymphoma	Daunorubicin
Neoplasms by Histologic Type	Dexamethasone
Neoplasms	Etoposide
Lymphoproliferative Disorders	Prednisolone
Lymphatic Diseases	Methylprednisolone Hemisuccinate
Immunoproliferative Disorders	Prednisone
Immune System Diseases	Vincristine
6-Mercaptopurine	BB 1101
Cytarabine	Dexamethasone acetate
Methotrexate	Methylprednisolone acetate
Thioguanine	Prednisolone acetate
Busulfan	Methylprednisolone
Cyclophosphamide	

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