ALL-REZ BFM 2002: Multi-Center Study for Children With Relapsed Acute Lymphoblastic Leukemia

The recruitment status of this study is unknown because the information has not been verified recently.
Verified August 2009 by Charite University, Berlin, Germany. Recruitment status was Recruiting

First Received on June 14, 2005. Last Updated on August 21, 2009 History of Changes

Sponsor:	Charite University, Berlin, Germany
Collaborator:	Deutsche Kinderkrebsstiftung
Information provided by:	Charite University, Berlin, Germany
ClinicalTrials.gov Identifier:	NCT00114348

Purpose

The protocol ALL-REZ BFM 2002 aims at the optimization of treatment for children with relapsed acute lymphoblastic leukemia. The primary objective of study ALL-REZ BFM 2002 is the randomized comparison of a lower dosed and less intensive, but continuous consolidation therapy with conventional therapy administered in treatment blocks. Outcome measures are the reduction of minimal residual disease (MRD), event-free and overall survival, and the toxicity associated with each treatment strategy.

Condition	Intervention
Lymphoblastic Leukemia, Acute Lymphoma, Non-Hodgkin	Procedure: R-Blocks Procedure: Protocol II-Ida

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: ALL-REZ BFM 2002: Protocol for the Treatment of Children With Relapsed Acute Lymphoblastic Leukemia

Resource links provided by NLM:

MedlinePlus related topics: Acute Lymphocytic Leukemia Chronic Lymphocytic Leukemia Leukemia Lymphoma

U.S. FDA Resources

Further study details as provided by Charite University, Berlin, Germany:

Primary Outcome Measures:

- Reduction of MRD
- event-free and overall survival
- the toxicity associated with each treatment strategy

Secondary Outcome Measures:

- Improvement of the prognosis in the intermediate risk group using the stratification in treatment arms with and without allogenic SCT based on the MRD result after the second treatment element of induction therapy

Estimated Enrollment: 338
Study Start Date: August 2003
Estimated Study Completion Date: July 2007

Detailed Description:
The study is based on the results of five consecutive trials performed by the ALL-REZ BFM study group since 1983. Thus the study meets the criteria of evidence-based therapy, which has been developed over nearly 20 years. Multi-agent chemotherapy in short intensive courses, which are separated by treatment-free intervals, has proved to be a successful form of induction and consolidation therapy. It is followed by preventative (or therapeutic) cranial irradiation and continuation therapy. A number of risk factors, particularly the time of relapse, site of relapse, and the ALL immunophenotype, allow the stratification of patients into a group that has an acceptable prognosis after treatment with chemotherapy alone and a second group that has a high risk of subsequent recurrence following the achievement of a second remission. The latter group requires further intensification of consolidation therapy by allogenic stem cell transplantation (SCT). To date, the indication for SCT has remained unclear for a large and heterogeneous group of patients with an intermediate prognosis. During the precursor study ALL-REZ BFM 96, however, the amount of minimal residual disease (MRD) determined quantitatively with clonal molecular markers after the second induction therapy element was shown to be a highly significant predictor of relapse-free survival.

The primary objective of study ALL-REZ BFM 2002 is the randomized comparison of a lower dosed and less intensive, but continuous consolidation therapy with conventional therapy administered in treatment blocks. Outcome measures are the reduction of MRD, event-free and overall survival, and the toxicity associated with each treatment strategy.

The secondary objectives include an improvement of the prognosis in the intermediate risk group using the stratification in treatment arms with and without allogenic SCT based on the MRD result after the second treatment element of induction therapy. An additional aim is to improve the remission induction rate in all groups by increasing the treatment intensity during induction. This is achieved by shortening the intervals between treatment blocks in keeping with the principles of guiding therapy as defined in the protocol. A series of biological companion studies aims to

advance our understanding of the disorder and to establish novel prognostic factors that will allow a risk-adapted therapy.

Eligibility

Ages Eligible for Study: up to 18 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Up to 18 years of age
- Morphologically confirmed diagnosis of relapsed non-B ALL or non-B non-Hodgkin lymphoma

Exclusion Criteria:

- They have completed the 18th year of life at the time the relapse is diagnosed.
- Curative therapy is declined either by patient himself/herself or the respective legal guardian
- The patient is pregnant
- The patient is breast feeding
- Essential parts of the relapse therapy are declined either by the patient or his/her legal cannot be administered because of medical reasons.
- No consent is given for transmission of data
- The patient has a severe concomitant disease that does not allow treatment according to protocol (e.g. malformation syndromes, cardiac malformations, metabolic disorders).

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00114348

Locations

Germany

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Contact: Andrea Kretschmann +49 (0)30 450 566 354 allrez@charite.de
Principal Investigator: Günter Henze, Prof.Dr.med.

Sponsors and Collaborators

Charite University, Berlin, Germany

Deutsche Kinderkrebsstiftung

Investigators

Principal Investigator: Günter Henze, Prof.Dr.med. GPOH

More Information

Additional Information:

ALL-REZ BFM 2002 EXIT

Publications:

Taube T, Eckert C, Korner G, Henze G, Seeger K. Real-time quantification of TEL-AML1 fusion transcripts for MRD detection in relapsed childhood acute lymphoblastic leukaemia. Comparison with antigen receptor-based MRD quantification methods. Leuk Res. 2004 Jul;28(7):699-706.

Eckert C, Einsiedel HG, Hartmann R, von Stackelberg A, Volpel S, Guggemos A, Hanzsch N, Kawan L, Seeger K, Henze G. Clonal stability of initial leukemia in a child with central nervous system relapse 7.4 years after bone marrow relapse of common acute lymphoblastic leukemic. Haematologica. 2004 Jul;89(7):ECR23.

Wellmann S, Guschmann M, Griethe W, Eckert C, von Stackelberg A, Lottaz C, Moderegger E, Einsiedel HG, Eckardt KU, Henze G, Seeger K. Activation of the HIF pathway in childhood ALL, prognostic implications of VEGF. Leukemia. 2004 May;18(5):926-33. Erratum in: Leukemia. 2004 Jun;18(6):1164. Stackelberg Av [corrected to von Stackelberg A].

Herold R, von Stackelberg A, Hartmann R, Eisenreich B, Henze G. Acute lymphoblastic leukemia-relapse study of the Berlin-Frankfurt-Munster Group (ALL-REZ BFM) experience: early treatment intensity makes the difference. J Clin Oncol. 2004 Feb 1;22(3):569-70; author reply 570-1. No abstract available.

Additional publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Willer A, Gerss J, König T, Franke D, Kühnel HJ, Henze G, von Stackelberg A, Möricke A, Schrappe M, Boos J, Lanvers-Kaminsky C. Anti-Escherichia coli asparaginase antibody levels determine the activity of second-line treatment with pegylated E coli asparaginase: a retrospective analysis within the ALL-BFM trials. Blood. 2011 Nov 24;118(22):5774-82. Epub 2011 Sep 22.

Shalapour S, Hof J, Kirschner-Schwabe R, Bastian L, Eckert C, Prada J, Henze G, von Stackelberg A, Seeger K. High VLA-4 expression is associated with adverse outcome and distinct gene expression changes in childhood B-cell precursor acute lymphoblastic leukemia at first relapse. Haematologica. 2011 Nov;96(11):1627-35. Epub 2011 Aug 9.

ClinicalTrials.gov Identifier: NCT00114348 History of Changes
Other Study ID Numbers: A2002/6a
Study First Received: June 14, 2005
Last Updated: August 21, 2009
Health Authority: Germany: Ethics Commission

Keywords provided by Charite University, Berlin, Germany:
non-B ALL

relapse
treatment
Relapsed non-B ALL or non-B non-Hodgkin lymphoma

Additional relevant MeSH terms:

Leukemia	Neoplasms
Leukemia, Lymphoid	Lymphoproliferative Disorders
Precursor Cell Lymphoblastic Leukemia-Lymphoma	Lymphatic Diseases
Lymphoma	Immunoproliferative Disorders
Lymphoma, Non-Hodgkin	Immune System Diseases
Acute Disease	Disease Attributes
Neoplasms by Histologic Type	Pathologic Processes

ClinicalTrials.gov processed this record on February 02, 2012