Pediatric Philadelphia Positive Acute Lymphoblastic Leukemia

This study is ongoing, but not recruiting participants.

Sponsor:
Bristol-Myers Squibb

Collaborators:
Children's Oncology Group
EsPhALL - European Intergroup Study on Post Induction Treatment of Philadelphia Positive Acute Lymphoblastic Leukaemia with Imatinib

Information provided by (Responsible Party):
Bristol-Myers Squibb

ClinicalTrials.gov Identifier:
NCT01460160

First received: October 25, 2011
Last updated: April 12, 2016
Last verified: September 2015
History of Changes

Purpose

The purpose of this study is to determine whether Dasatinib when added to standard chemotherapy is effective and safe in the treatment of pediatric philadelphia chromosome positive acute lymphoblastic leukemia

Condition	Intervention	Phase
Leukemia, Pediatric	Drug: Dasatinib	Phase 2

Study Type: Interventional
Study Design: Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Phase 2 Multi-Center, Historically Controlled Study of Dasatinib Added to Standard Chemotherapy in Pediatric Patients With Newly Diagnosed Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia

Resource links provided by NLM:

MedlinePlus related topics: Chronic Lymphocytic Leukemia Leukemia

Drug Information available for: Dasatinib

Genetic and Rare Diseases Information Center resources: Acute Lymphoblastic Leukemia Lymphosarcoma

U.S. FDA Resources

Further study details as provided by Bristol-Myers Squibb:

Primary Outcome Measures:

- Event free survival (EFS) rate at 3 years of Dasatinib plus chemotherapy compared with external historical controls [Time Frame: Three years following the 75th patient's first visit] [Designated as safety issue: No]

Secondary Outcome Measures:

- Safety and feasibility of Dasatinib added to standard chemotherapy [Time Frame: Up to 2 years from first dose of Dasatinib] [Designated as safety issue: Yes]

  Based on adverse events and laboratory results

- Event free survival rate at 3 and 5 years [Time Frame: 3 and 5 years following the 75th patient's first visit] [Designated as safety issue: No]
- Minimal Residual Disease levels [Time Frame: At approximately 2 weeks, 8 weeks, 20 weeks after starting Dasatinib and at progression (up to 5 years after last dose of Dasatinib)] [Designated as safety issue: No]
- Complete Remission Rates [Time Frame: At 8 weeks and between week 17 and 20 after starting Dasatinib] [Designated as safety issue: No]

Complete remission will be defined as <5% lymphoblasts in bone marrow (ie M1 bone marrow) and Cerebrospinal Fluid (CSF) with no evidence of other extramedullary disease at end of induction compared with AIEOP BFM 2000 and the Amended EsPhALL trials AIEOP = Associazione Italiana di Ematologia Pediatrica BFM = Berlin-Frankfurt-Müenster Leukemia Backbone Therapy EsPhALL = European InterGroup Study on Post Induction Treatment of Philadelphia Positive Acute Lymphoblastic Leukemia

- Oncogene fusion protein (BCR-ABL) mutation status [Time Frame: Baseline (Induction phase 1B) and time of disease progression or relapse (Approximately up to 5 years)] [Designated as safety issue: No]

  BCR-ABL mutation is defined as the presence of a detectable amino acid substitution in the ABL kinase domain

Estimated Enrollment:	75
Study Start Date:	January 2012
Estimated Study Completion Date:	May 2021
Estimated Primary Completion Date:	May 2017 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Arm 1: Dasatinib	Drug: Dasatinib Tablets, Oral, 60 mg/m2, Once daily, 2 years or until unacceptable toxicity Other Name: Sprycel

Eligibility

Ages Eligible for Study:	1 Year to 17 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

For more information regarding BMS clinical trial participation, please visit www.BMSStudyConnect.com.

Inclusion Criteria:

- Newly diagnosed Philadelphia chromosome positive Acute Lymphoblastic Leukemia (ALL)
- Age >1 year and < less than 18 years old
- Induction chemotherapy ≤ 14 days according to institutional standard of care
- Adequate liver, renal and cardiac function

Exclusion Criteria:

- Prior treatment with a Oncogene fusion protein (BCR-ABL) inhibitor
- Extramedullary involvement of the testicles
- Active systemic bacterial, fungal or viral infection
- Down syndrome

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01460160

Show 128 Study Locations

Sponsors and Collaborators

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Children's Oncology Group

EsPhALL - European Intergroup Study on Post Induction Treatment of Philadelphia Positive Acute Lymphoblastic Leukaemia with Imatinib

Investigators

Study Director: Bristol-Myers Squibb Bristol-Myers Squibb

More Information

Additional Information:

BMS Clinical Trial Information EXIT

BMS clinical trial educational resource EXIT

Investigator Inquiry form

FDA Safety Alerts and Recalls

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Other Study ID Numbers:	**CA180-372** 2011-001123-20 AALL1122
Study First Received:	October 25, 2011
Last Updated:	April 12, 2016
Health Authority:	United States: Food and Drug Administration Canada: Health Canada Australia: Department of Health and Ageing Therapeutic Goods Administration United Kingdom: Medicines and Healthcare Products Regulatory Agency Italy: Ministry of Health Italy: National Bioethics Committee Italy: National Institute of Health Italy: National Monitoring Centre for Clinical Trials - Ministry of Health Italy: The Italian Medicines Agency

Additional relevant MeSH terms:

Leukemia	Neoplasms
Leukemia, Lymphoid	Neoplasms by Histologic Type
Precursor Cell Lymphoblastic Leukemia-Lymphoma	Dasatinib
Immune System Diseases	Enzyme Inhibitors
Immunoproliferative Disorders	Molecular Mechanisms of Pharmacological Action
Lymphatic Diseases	Pharmacologic Actions
Lymphoproliferative Disorders	Protein Kinase Inhibitors

ClinicalTrials.gov processed this record on April 24, 2016