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Studying First Line Treatment of Chronic Myeloid Leukemia (CML) in a Real-world Setting (SIMPLICITY)

This study is currently recruiting participants.

Verified October 2013 by Bristol-Myers Squibb

Sponsor:
Bristol-Myers Squibb

Collaborator:
ICON Clinical Research

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

ClinicalTrials.gov Identifier:
NCT01244750

First received: November 15, 2010
Last updated: October 21, 2013
Last verified: October 2013
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

The purpose of this study is to better understand the use of tyrosine kinase inhibitors (TKI) in patients newly diagnosed with CML and their quality of life in a real-world setting.

Condition
Chronic Myeloid Leukemia

Study Type: Observational
Study Design: Observational Model: Cohort

Official Title: Studying Interventions for Managing Patients With Chronic Myeloid Leukemia (CML) in Chronic Phase: The 5-Year Prospective Cohort Study (SIMPLICITY)

Resource links provided by NLM:

MedlinePlus related topics: Chronic Myeloid Leukemia Leukemia

Drug Information available for: Imatinib Imatinib mesylate

U.S. FDA Resources

Further study details as provided by Bristol-Myers Squibb:

Primary Outcome Measures:

- The rate of Complete Cytogenetic Response [Time Frame: 12 months] [Designated as safety issue: No]
- The duration of initial TKI treatment [Time Frame: 5-years from study index date] [Designated as safety issue: No]

  Initiation of first-line TKI, (whether Dasatinib, Imatinib, Nilotinib)

- The rate of discontinuation and treatment changes after initial TKI treatment [Time Frame: Every 6 months for a follow-up period of 5-years from study index date] [Designated as safety issue: No]

  Dates of switches in therapy from initial TKI treatment, Reasons for treatment discontinuation (i.e. side effects, mutations, etc.), Subsequent lines of CML treatments (start and stop dates)

- The rate of best response to therapy (i.e. hematologic, cytogenetic, molecular response) [Time Frame: Every 6 months for a follow-up period of 5-years from study index date] [Designated as safety issue: No]

  Results and dates of: all bone marrow aspirates, blood tests, cytogenetics, Polymerase Chain Reaction (PCR), Fluorescent In-Situ Hybridization (FISH), and Physical exam

- The adherence to treatment [Time Frame: Every 6 months for a follow-up period of 5-years from study index date] [Designated as safety issue: No]

  Morisky Medication Adherence Scale - 8 Items is a validated self-reported measure of medication adherence.

Secondary Outcome Measures:

- Impact of first-line treatment options on quality of life [Time Frame: Every 6 months] [Designated as safety issue: No]

  Questionnaires used for assessment: Functional Assessment of Cancer Therapy - General (FACT-G), Cancer Therapy Satisfaction Questionnaire (CTSQ), MD Anderson Symptom Inventory - CML (MDASI-CML).

- Non-hematologic side effects from treatment affecting patient quality of life and outcomes [Time Frame: Every 6 months] [Designated as safety issue: No]

  Treatment discontinuations and changes

- Patient satisfaction with CML treatment [Time Frame: Every 6 months] [Designated as safety issue: No]

  Cancer Therapy Satisfaction Questionnaire (CTSQ)

- Patterns of disease monitoring as observed in a real-world setting [Time Frame: Every 6 months] [Designated as safety issue: No]

  MD Anderson Symptom Inventory - CML (MDASI-CML) Questionnaire - disease-specific module of the MDASI7 which is a brief measure of severity and impact of cancer-related symptoms on daily function

- Resource utilization associated with CML management [Time Frame: Every 6 months] [Designated as safety issue: No]

  To evaluate healthcare resource utilization, descriptive statistics will describe real-world disease monitoring patterns, frequency of testing, and resources used for disease management for each treatment cohort.

Estimated Enrollment:	1400
Study Start Date:	October 2010
Estimated Study Completion Date:	December 2017
Estimated Primary Completion Date:	December 2017 (Final data collection date for primary outcome measure)

Groups/Cohorts

First line TKI treatment: Imatinib Diagnosed CML patients who receive first line TKI treatment: Imatinib
First line TKI treatment: Nilotinib Diagnosed CML patients who receive first line TKI treatment: Nilotinib
First line TKI treatment: Dasatinib Diagnosed CML patients who receive first line TKI treatment: Dasatinib
Imatinib treated patients Imatinib treated patients if their study index date is between January 2, 2008 and September 30, 2010

Detailed Description:

Time Perspective : Most patients are expected to be a mix of retrospective and prospective data collection. Patients can be enrolled after their study index date (retrospective component) and have to be followed until 5 years from study index date are complete (time between enrollment and 5 year follow-up is the prospective component)

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No
Sampling Method:	Non-Probability Sample

Study Population

Patients will be recruited at oncology practices or oncology centers linked to a hospital in the North Americas, Europe and potentially at additional sites in South America, and Asia

Criteria

For additional information, please contact the BMS oncology clinical trial information service at 855-216-0126 or email MyCancerStudyConnect@emergingmed.com. Please visit www.BMSStudyConnect.com for more information on clinical trial participation.

Inclusion Criteria:

- Newly-diagnosed chronic phase chronic myeloid leukemia (CP-CML) patients who started their first-line Tyrosine Kinase Inhibitor (TKI) treatment on imatinib, dasatinib or nilotinib in accordance with the timelines below

- 18 years or older at time of of CP-CML diagnosis a) Imatinib Cohorts
- Patients who started their first-line Imatinib treatment between January 2, 2008 and September 30, 2010.Patients fitting this criterion are defined as retrospective Imatinib patients − Patients who started their first-line Imatinib treatment on or after October 1, 2010 b) Dasatinib Cohort
- Patients who started their first-line Dasatinib treatment after the drug was approved in this indication c) Nilotinib Cohort
- Patients who started their first-line Nilotinib treatment after the drug was approved in this indication
- Patients are also eligible when they have already switched to a subsequent therapy (TKI or other) at the time of enrollment, as long as their first-line and subsequent CML treatment information is available at site for data entry into the study Electronic Case Report Form (eCRF)
- Receiving treatment at medical practice (eg. community-based, office-based, hospital-based, academic setting, oncology center)

Exclusion Criteria:

- Patients who are participating in an interventional trial which may influence the management of their CML disease will be excluded

Discontinuation Criteria:

- Enrolled patients who join an interventional trial which may influence the management of their CML disease will be excluded at the time of entry into the interventional trial

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01244750

Contacts

Contact: For participation information at a USA site use a phone number below. For Site information outside USA please email: clinical.trials@bms.com

Contact: First line of email MUST contain NCT# & Site#. Only trial site that are recruiting have contact information at this time.

Show 217 Study Locations

Sponsors and Collaborators

Bristol-Myers Squibb

ICON Clinical Research

Investigators

Study Director: Bristol-Myers Squibb Bristol-Myers Squibb

More Information

Additional Information:

BMS Clinical Trials Disclosure EXIT

Investigator Inquiry form EXIT

For FDA Safety Alerts and Recalls refer to the following link: http://www.fda.gov/MEDWATCH/safety.htm EXIT

No publications provided

Responsible Party:	Bristol-Myers Squibb
ClinicalTrials.gov Identifier:	NCT01244750 History of Changes
Other Study ID Numbers:	CA180-330
Study First Received:	November 15, 2010
Last Updated:	October 21, 2013
Health Authority:	United States: Institutional Review Board

Keywords provided by Bristol-Myers Squibb:
Chronic Phase - Chronic Myeloid Leukemia

Additional relevant MeSH terms:

Leukemia	Neoplasms
Leukemia, Myeloid	Myeloproliferative Disorders
Leukemia, Myelogenous, Chronic, BCR-ABL Positive	Bone Marrow Diseases
Neoplasms by Histologic Type	Hematologic Diseases

ClinicalTrials.gov processed this record on December 08, 2013