Purpose

CML requires ongoing treatment and assessment of treatment milestones in order to manage the disease properly. Dasatinib is approved for the treatment of newly diagnosed Ph+ CP-CML and CML in chronic or accelerated phase or blast crisis in patients resistant or intolerant to prior therapies including Imatinib. Although Imatinib has demonstrated unprecedented efficacy in clinical trials, mostly in chronic phase CML, there is lack of published data on how CML is managed in real-life clinical practice settings. Therefore, this non-interventional study is designed to collect real-life data on CML-treatment with Dasatinib in clinical routine with respect to first and second line treatment and/or switch setting (within 1st line or from 1st line TKI to 2nd line Dasatinib). Emphasis lies on health care provided in registered doctor's practices as here most of CML patients who are not involved in clinical trials are treated.

Condition

- Myeloid Leukemia, Chronic, Chronic-Phase

Study Type: Observational
Study Design: Time Perspective: Prospective

Official Title: Treating Patients With Chronic Myeloid Leukemia (CML) in Chronic Phase (CP) With Dasatinib PCR-Monitoring, Adherence, Quality of Life, Therapy Satisfaction

Resource links provided by NLM:

- MedlinePlus related topics: Chronic Myeloid Leukemia, Leukemia
- Drug Information available for: Dasatinib
- Genetic and Rare Diseases Information Center resources: Chronic Myeloid Leukemia, Chronic Myeloproliferative Disorders, Myeloid Leukemia
- U.S. FDA Resources

Further study details as provided by Onco Medical Consult GmbH:

Primary Outcome Measures:

- Distribution of Molecular remission status at study entry and after 12 months. [Time Frame: 12 Months] [Designated as safety issue: No]
  Patients included into this study are on a treatment with Dasatinib. Fraction of BCR-ABL positive cells is measured at study entry or was assessed at the time point of Dasatinib treatment begin and classified as >MR3, MR3, MR4, and MR4.5 as an ordinal measure. Molecular Fraction of BCR-ABL positive cells is reassessed after 12 months.

Secondary Outcome Measures:

- Distribution of Molecular remission status at study entry and after 24 months. [Time Frame: 24 months] [Designated as safety issue: No]
  Patients included into this study are on a treatment with Dasatinib. Fraction of BCR-ABL positive cells is measured at study entry or was assessed at the time point of Dasatinib treatment begin and classified as >MR3, MR3, MR4, and MR4.5 as an ordinal measure. Molecular Fraction of BCR-ABL positive cells is reassessed after 24 months.

- Best possible response [Time Frame: Up to 36 months] [Designated as safety issue: No]
  Defined as the best response at any time after the start of the treatment. Reported will be distributions for each response (progression, stable disease, remission for at least one class of MR)

- Time to Molecular remission [Time Frame: up to 36 months] [Designated as safety issue: No]
  Patients reach this event, when a change from a higher amount of BCR-ABL positive patients to a lower amount of BCR-ABL positive patients occurs

- Time molecular progression [Time Frame: Up to 36 months] [Designated as safety issue: No]
Although Imatinib has demonstrated exceptional efficacy in clinical trials, mostly in chronic phase CML, there is lack of published data on how CML is newly diagnosed PH+ CP-CML and CML in chronic or accelerated phase or blast crisis in patients resistant or intolerant to prior therapies including Imatinib. Nevertheless, further data are required to obtain additional information on the clinical benefits of Dasatinib. With better long-term, progression-free survival, Dasatinib may improve the long-term outcomes among patients with newly diagnosed chronic-phase CML.

A phase III study (DASISION) of Dasatinib vs. Imatinib could prove that Dasatinib induced significantly higher and faster rates of complete cytogenetic response and major molecular response when compared to Imatinib. Since achieving complete cytogenetic response within 12 months has been associated with better long-term, progression-free survival, Dasatinib may improve the long-term outcomes among patients with newly diagnosed chronic-phase CML.

According to the summary of product characteristics brochure Dasatinib (Sprycel®) is indicated for the treatment of adult patients with:

- Chronic, accelerated or blast phase CML with resistance or intolerance to prior therapy including Imatinib mesilate.
- New ly diagnosed Ph+ acute lymphoblastic leukaemia and lymoid blast CML w ith resistance or intolerance to prior therapy.
- Ph+ acute lymphoblastic leukaemia and lymoid blast CML with resistance or intolerance to prior therapy.

In June 2006, the U.S. Food and Drug Administration (FDA) granted accelerated approval for Dasatinib to treat adults with CP-CML with resistant disease or who were intolerant to prior therapy, including Imatinib. The FDA converted Dasatinib to a regular approval in May 2009, after confirmation of the treatment's safety and effectiveness. On October 28, 2010, FDA granted accelerated approval to Dasatinib for the treatment of new ly diagnosed adult patients w ith CML-CP. Dasatinib entered thereby a marketplace w ith other TKIs including Nilotinib.

CML requires ongoing treatment and assessment of treatment milestones in order to manage the disease properly. Dasatinib is approved for the treatment of newly diagnosed Ph+ CP-CML and CML in chronic or accelerated phase or blast crisis in patients resistant or intolerant to prior therapies including Imatinib. Although Imatinib has demonstrated exceptional efficacy in clinical trials, mostly in chronic phase CML, there is lack of published data on how CML is...
managed in real-life clinical practice settings. Therefore this non-interventional study is designed to collect real-life data on CML-treatment with Dasatinib in clinical routine with respect to first and second line treatment and/or switch setting (within 1st line or from 1st line TKI to 2nd line Dasatinib). Emphasis lies on health care provided in registered doctor’s practices as here most of CML patients who are not involved in clinical trials are treated.

Eligibility

Ages Eligible for Study: 18 Years to 80 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No
Sampling Method: Non-Probability Sample

Study Population

This non-interventional study will document around 300 adult patients with newly-diagnosed CP-CML and CML patients in chronic phase resistant or intolerant to prior therapies, including Imatinib and Nilotinib.

Criteria

Inclusion Criteria:
- Patients with newly diagnosed CP-CML and CML patients in chronic phase resistant or intolerant to prior therapies, including Imatinib. Any line treatment of chronic CML.
- 18 years or older at time of diagnosis
- Receiving treatment with Dasatinib according to the SmPC
- Written informed consent obtained before any screening procedure and according to local guidelines

Exclusion Criteria:
- Patients who are participating in a clinical trial for CML treatment will be excluded

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: NCT02348957

Contacts

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Locations

Germany
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- Recruiting Altötting, Bayern, Germany, 84503
- Recruiting Aschaffenburg, Bayern, Germany, 63739
- Recruiting Kronach, Bayern, Germany, 96317
- Recruiting München, Bayern, Germany, 80335
- Recruiting München, Bayern, Germany, 80331
- Recruiting Potsdam, Brandenburg, Germany, 14467
- Recruiting Goslar, Niedersachsen, Germany, 38642
- Recruiting Hamm, Nordrhein-Westfalen, Germany, 59065
- Recruiting Idar-Oberstein, Rheinland-Pfalz, Germany, 55743
- Recruiting Kaiserslautern, Rheinland-Pfalz, Germany, 67655
- Recruiting Koblenz, Rheinland-Pfalz, Germany, 56068
- Recruiting Leipzig, Sachsen, Germany, 04289
- Recruiting Augsburg, Germany, 86150
Recruiting
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Recruiting
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Recruiting
Frankfurt am Main, Germany, 60389
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Recruiting
Heidenheim, Germany, 89518
Recruiting
Herne, Germany, 44623
Recruiting
Hof, Germany, 95028
Recruiting
Köln, Germany, 51103
Recruiting
Köln, Germany, 50677
Recruiting
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Recruiting
München, Germany, 81241
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More Information
No publications provided

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Chronic myeloid leukemia
Dasatinib
Any line
Chronic phase

Additional relevant MeSH terms:
Leukemia
Leukemia, Myelogenous, Chronic, BCR-ABL Positive
Leukemia, Myeloid
Leukemia, Myeloid, Chronic-Phase
Bone Marrow Diseases
Hematologic Diseases
Myeloproliferative Disorders

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