Treating Patients With Chronic Myeloid Leukemia (CML) in Chronic Phase (CP) With Dasatinib (DasPAQT)

This study is currently recruiting participants. (see Contacts and Locations)

Verified January 2015 by Onco Medical Consult GmbH

Sponsor:
Onco Medical Consult GmbH

Information provided by (Responsible Party):
Onco Medical Consult GmbH

ClinicalTrials.gov Identifier:
NCT02348957

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History of Changes

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 timepoint 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]

Patients start the observation period at study entry and reach this event, when a change to a higher BCR-ABL remission status is reached.

- Cytogenetic profile at start of Dasatinib treatment, type of BCR-ABL transcript (if these parameters are routinely tested at the facility and are documented for the NIS). [Time Frame: Up to 36 months] [Designated as safety issue: Yes]

  Cytogenetic response according to conventional cytogenetics (evaluation of at least 20 metaphase chromosomes) and hyper metaphase FISH (if applicable)

- Hematologic response (HR) and complete blood count (if these parameters are routinely tested at the facility and are documented for the NIS) [Time Frame: Up to 36 months] [Designated as safety issue: No]

  Complete blood count (if these parameters are routinely tested at the facility and are documented for the NIS

- Patient Compliance/Adherence [Time Frame: After 3,6,12,24 months] [Designated as safety issue: No]

  Assessed at Baseline and analyzed over time after 3,6,12,24 months of observation.

- Patients' Satisfaction [Time Frame: After 3,6,12,24 months] [Designated as safety issue: No]

  Assessed at Baseline and analyzed over time after 3,6,12,24 months of observation.

- Quality of Life [Time Frame: Time after 3,6,12,24 months] [Designated as safety issue: No]

  Assessed at Baseline and analyzed over time after 3,6,12,24 months of observation.

- Number of Participants with Adverse Events as a Measure of Safety and Tolerability [Time Frame: Time after 3,6,12,24 months] [Designated as safety issue: No]

  Assessed at Baseline and analyzed over time after 3,6,12,24 months of observation.

- Subgroup analysis concerning the primary study objective [Time Frame: 12 months] [Designated as safety issue: No]

  Common influencing factors like prognostic scores or previous therapy patterns are analyzed, whether they have an influence on the primary study aim.

- Subgroup analysis concerning the time to remission [Time Frame: Up to 36 months] [Designated as safety issue: No]

  Common influencing factors like prognostic scores or previous therapy patterns are analyzed, whether they have an influence on time to remission

- Subgroup analysis concerning the time to progression [Time Frame: Up to 36 months] [Designated as safety issue: No]

  Common influencing factors like age, sex or previous therapy patterns are analyzed, whether they have an influence on time to progression

- Subgroup analysis concerning the quality of life and patient compliance [Time Frame: Time after 3,6,12,24 months] [Designated as safety issue: No]

  Common influencing factors like age, sex, comorbidities or previous therapy patterns are analyzed, whether they have an influence on quality of life and patient compliance

- Subgroup analyses of participants with Adverse Events as a Measure of Safety and Tolerability [Time Frame: Time after 3,6,12,24 months] [Designated as safety issue: No]

  Common influencing factors like age, sex, comorbidities or previous therapy patterns are analyzed, whether they have an influence on safety and toxicity

Estimated Enrollment:	300
Study Start Date:	October 2014
Estimated Study Completion Date:	April 2019
Estimated Primary Completion Date:	December 2018 (Final data collection date for primary outcome measure)

Detailed Description:

The advent of Imatinib into the market in 2001 changed the treatment paradigm of CML. Seven-year follow-up from the IRIS trial revealed an estimated overall survival of 86% in newly diagnosed CML patients treated with Imatinib.

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 newly diagnosed adult patients with CML-CP. Dasatinib entered thereby a marketplace with other TKIs including Nilotinib.

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

- Newly diagnosed Ph+ CML In the chronic phase.
- Chronic, accelerated or blast phase CML with resistance or intolerance to prior therapy including Imatinib mesilate.
- Ph+ acute lymphoblastic leukaemia and lymoid blast CML with resistance or intolerance to prior therapy.

A phase III study (DASISION) of Dasatinib vs. Imatinib could proof 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.

Nevertheless, further data are required to obtain additional information on the clinical benefits of Dasatinib.

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 w ith Dasatinib in clinical routine w ith respect to first and second line treatment and/or sw itch setting (w ithin 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 w ho 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 w ill document around 300 adult patients w ith new ly-diagnosed CP-CML and CML patients in chronic phase resistant or intolerant to prior therapies, including Imatinib and Nilotinib.

Criteria

Inclusion Criteria:

- Patients w ith new ly 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 w ith Dasatinib according to the SmPC
- Written informed consent obtained before any screening procedure and according to local guidelines

Exclusion Criteria:

•Patients w ho are participating in a clinical trial for CML treatment w ill be excluded

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk w ith 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

Contact: Cornelia Schneider-Schranz, PhD	0049 69 560056 18	Cornelia.Schneider@chop-studien.de
Contact: Oliver EL Knapp, PhD	0049 931 359200 68	knapp@clin-sol.com

Locations

Germany

Recruiting
Schw äbisch Hall, Baden-Württemberg, Germany, 74523

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
Bad Soden, Germany, 65812

Recruiting
Duisburg, Germany, 47166

Recruiting
Frankfurt am Main, Germany, 60389

Recruiting
Hannover, Germany, 30171

Recruiting
Heidenheim, Germany, 89518

Recruiting
Herne, Germany, 44623

Recruiting
Hof, Germany, 95028

Recruiting
Köln, Germany, 51103

Recruiting
Köln, Germany, 50677

Recruiting
Landshut, Germany, 84028

Recruiting
München, Germany, 81241

Recruiting
Neustadt am Rübenberge, Germany, 31535

Recruiting
Singen, Germany, 78224

Recruiting
Trier, Germany, 54292

Recruiting
Westerstede, Germany, 26655

Sponsors and Collaborators

Onco Medical Consult GmbH

Investigators

Principal Investigator: Hans Tesch, Prof. Dr. Hämatologisch-Onkologische Gemeinschaftspraxis am Bethanien-Krankenhaus, Im Prüfling 17, D-60389 Frankfurt am Ma

More Information

No publications provided

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Keywords provided by Onco Medical Consult GmbH:
Chronic myeloid leukemia
Dasatinib
Any line
Chronic phase

Additional relevant MeSH terms:

Leukemia	Neoplasms
Leukemia, Myelogenous, Chronic, BCR-ABL Positive	Neoplasms by Histologic Type
Leukemia, Myeloid	Dasatinib
Leukemia, Myeloid, Chronic-Phase	Enzyme Inhibitors
Bone Marrow Diseases	Molecular Mechanisms of Pharmacological Action
Hematologic Diseases	Pharmacologic Actions
Myeloproliferative Disorders	Protein Kinase Inhibitors

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