Evaluate the Real-World Safety Outcomes and Clinical Efficacy of Ponatinib and Other Tyrosine Kinase Inhibitors among Chronic Myeloid Leukemia Patients

First published: 15/02/2023

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS50308

Study ID

50309

DARWIN EU® study

No

Study countries

United States

Study description

The aims of this study are to learn out about treatment information (including amongst others treatment patterns, safety, development of a participant's condition) ponatinib, bosutinib, imatinib, dasatinib and nilotinib using already available data. No new data will be collected from participants as part of this study and no study medicines will be provided in this study.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

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Institution

Contact details

Study institution contact

Study Contact Takeda TrialDisclosures@takeda.com

Study contact

TrialDisclosures@takeda.com

Primary lead investigator

Study Contact Takeda

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 06/10/2021

Study start date
Actual: 24/07/2020

Data analysis start date
Actual: 24/07/2020

Date of interim report, if expected
Actual: 22/12/2021

Date of final study report
Actual: 30/11/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

Takeda_Protocol_CML_Humedica_24JULY2020_redacted_12 Jan 2024.pdf (4.79 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The main objective of this study is using Humedica Electronic Health Records (EHR) data from October 1, 2012—September 30, 2017 (or the most recent 5 years of data), STATinMED Research proposes to evaluate the real-world treatment patterns and clinical outcomes of ponatinib and other Tyrosine Kinase Inhibitors (TKIs) among patients with prior TKI uses among CP-CML participants.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Chronic myeloid leukaemia

Population studied

Short description of the study population

The study population included patients with chronic myeloid leukemia received treatment with ponatinib and other tyrosine kinase inhibitors identified from Humedica EMR data between October 1, 2012 to September 30, 2017.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Patients with chronic myeloid leukemia

Estimated number of subjects

1.769

Study design details

Outcomes

Participants Categorized by Socio-demographic Variables, Clinical Characteristics of Disease,Comorbidities Severity,Concomitant Medication,Bone Marrow Stem Cell Transplant,Major Adverse Cardiac Event(MACE),Arterial Occlusive Event(AOE), and Venous Thrombotic Events(VTE),Quan-Charlson Comorbidity Index Score,Number of Previous Treatments of TKI Drugs,Duration From Last TKI Run-out to Index Date. Participants With BCR-ABL,Bone Marrow Testing, Disease Severity as per Medstat Disease Staging Clinical Criteria Version 5.21, Treatment-Free Gap of the Index Treatment,Treatment Patterns Based on Duration of Index Treatment,Mean Starting Daily Dose and Average Daily Dose,Number of Participants With CML on Concomitant Medication.

Disease Progression, Progression Free Survival(PFS).

Data analysis plan

All variables will first be analyzed descriptively and compared across ponatinib, bosutinib, and other TKIs (imatinib, dasatinib, or nilotinib) for patients with prior TKI use. Numbers and percentages will be provided for dichotomous and polychotomous variables. Means and standard deviations will be provided for continuous variables. For dichotomous and polychotomous variables, p-values will be calculated according to the chi-square test, for continuous variables, t-tests will be used to calculate p-values. Ponatinib will be considered as the reference group for the comparisons.

Documents

Study report

GOR-2017-102256-clinical-study-report-redact.pdf (856.19 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s), other

Humedica EMR

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No