A PROSPECTIVE NON-INTERVENTIONAL SAFETY STUDY IN PATIENTS WITH CHRONIC MYELOID LEUKEMIA RECEIVING NILOTINIB IN DAILY PRACTICE ACCORDING TO UPDATED GUIDELINES

First published: 21/01/2013

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS3335

Study ID

16550

DARWIN EU® study

No

Study countries

Austria

Germany

Study description

This non-interventional, observational study will provide real-world safety data on CML CP patients exposed to nilotinib and therefore provide insights into disease management as well as the safety profile of nilotinib.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Institution

Multiple centres: 15 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Novartis Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/02/2013

Actual: 10/02/2013

Study start date

Planned: 26/08/2013

Actual: 10/10/2013

Data analysis start date

Planned: 01/07/2020

Actual: 31/12/2015

Date of final study report

Planned: 31/12/2016

Actual: 31/12/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharmaceuticals

Study protocol

CAMN107AAT01_Tasigna_PASS_Protocol_version01_Redacted.pdf (512.23 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

CAMN107AAT01

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

This observational study will provide real-world safety data on CML patients exposed to nilotinib and therefore provide insights into disease management, efficacy as well as the safety profile of nilotinib and the adherence to current treatment recommendations (Baccarani et al. 2009, Valent et al. 2011, Rosti et al. 2011) in daily clinical practice.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

TASIGNA

Study drug International non-proprietary name (INN) or common name

NILOTINIB

Anatomical Therapeutic Chemical (ATC) code

(L01XE08) nilotinib

nilotinib

Medical condition to be studied

Chronic myeloid leukaemia

Population studied

Short description of the study population

Patients with chronic myeloid leukemia receiving Nilotinib in daily practice.

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

Chronic myeloid leukaemia patients

Estimated number of subjects

100

Study design details

Outcomes

The main goal of this non-interventional study is to document the following parameters under specific conditions of daily clinical practice:• Safety and tolerability and all adverse events (AE, serious and non-serious) during treatment with nilotinib and adherence to current treatment recommendations in daily clinical practice, Clinical, cytogenetic, hematologic and molecular responses to nilotinib

Data analysis plan

There are no predefined hypotheses regarding the incidence of specific safety outcomes, the magnitude of effectiveness or treatment practices. Descriptive statistical methods will be used for all variables of evaluation. Efficacy and safety variables will be presented descriptive and will be interpreted in comparison to historic controls and published data.

Documents

Study results

CAMN107AAT01_Redacted CSR.pdf (612.58 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 sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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

Unknown