Prospective observational study to assess the long term safety profile of venetoclax in a Swedish cohort of Chronic Lymphocytic Leukaemia (CLL) patients

First published: 12/06/2017

Last updated: 06/05/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS19010

Study ID

49279

DARWIN EU® study

No

Study countries

☐ Sweden

Study description

A large national cohort of CLL patients will be identified based on data from the national health registers (National Patient Register, Swedish Cancer Registry, Swedish Prescribed Drug Register and Cause of Death Register), which will allow for capturing adverse events, co-morbidities, prescribed medication, surgical and other procedures (including whole body skin scans, when performed), outcomes/progression (including adverse events and new malignancies) and mortality data.

Research question and objectives:

• To characterize long term safety of venetoclax, including determining the incidence of selected adverse events in CLL patients exposed to venetoclax (Primary objective)

• To further characterize long term safety of venetoclax, by describing the treated patient population and factors associated with events of interest (Secondary objective a)

• To compare safety profile of venetoclax against alternative treatment modalities (Secondary objective b)

• To describe clinical characteristics of CLL patients at diagnosis such as age, gender, staging, comorbidities and prognostic factors (e.g. cytogenetic factors, renal and hepatic function) (Secondary objective c)

• To describe treatment regimens and sequence of therapy based on patient characteristics and risk factors (Exploratory objective)

• To assess any clinical outcome as a result of contraindicated medications use in patients who have received venetoclax in a real world setting.

Study status

Ongoing

Research institutions and networks

Institutions

IQVIA

United Kingdom

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Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Hansson Lotta

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 07/07/2017

Actual: 18/01/2018

Study start date
Planned: 30/11/2018

Actual: 02/01/2019

Data analysis start date
Planned: 01/01/2019

Actual: 26/09/2019

Date of interim report, if expected
Planned: 31/12/2019

Actual: 10/12/2020

Date of final study report
Planned: 31/03/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

p16-562-protocol-pmos-v3_redacted.pdf(3.1 MB)

p16562-protocol-pmos-v6_Redacted.pdf(1.95 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Other

If ‘other’, further details on the scope of the study

Adverse events assessment

Main study objective:

Main objective: To determine the incidence of selected adverse events (including Richter’s transformation) in CLL patients using venetoclax following long term use in the Real World.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

VENETOCLAX

Medical condition to be studied

Chronic lymphocytic leukaemia

Population studied

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)

Estimated number of subjects

3600

Study design details

Outcomes

The primary outcome is the incidence of selected adverse events in CLL patients treated with venetoclax. Adverse events will be stratified by selected

patient characteristics and risk factors. Information on adverse events will be captured via different sources (e.g. National Patient Register and Swedish Cancer Registry and EMRs).

Data analysis plan

Statistical analysis will be conducted separately for each objective. Time-to-event and case mix methodologies will be applied, as necessary (e.g. primary objective and secondary objective b). Incidence rates of adverse events will be calculated per unit of observational time. Adverse events will be stratified by relevant patient characteristics and risk factors. Descriptive analysis of patient and clinical characteristics will also be performed.

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)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

Electronic Medical Records Sweden, National Health registries Sweden

Data sources (types)

Disease registry

Drug dispensing/prescription data

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