An Active Safety Surveillance Program To Monitor Selected Events In Patients With Long-Term Voriconazole Use

First published: 03/03/2016

Last updated: 13/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS12624

Study ID

48463

DARWIN EU® study

No

Study countries

Sweden

Study description

This is an observational cohort study examining the safety profile of Voriconazole in adults and pediatric patients, particularly those with long-term Voriconazole use (≥180 days of treatment). The study will utilize data from Swedish National Registers including the Swedish Prescribed Drug Register (SPDR), the Swedish Cancer Register (SCR), the National Patient Register (NPR), the Causes of Death Register (CDR), and the Registers of Statistics Sweden.

Study status

Finalised

Research institutions and networks

Institutions

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden

First published: 24/03/2010

Last updated: 23/04/2024

Institution **Educational Institution** **Laboratory/Research/Testing facility** **Not-for-profit** **ENCePP partner**

Contact details

Study institution contact

Helle Kieler helle.kieler@ki.se

Study contact

helle.kieler@ki.se

Primary lead investigator

Helle Kieler

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 21/01/2016

Study start date

Planned: 01/09/2016

Actual: 12/04/2016

Data analysis start date

Actual: 14/11/2016

Date of final study report

Planned: 30/06/2022

Actual: 29/04/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc

Study protocol

Voriconazole__NIS_Protocol_A1501103_ ENCEPP SDPP 12624.pdf (754.82 KB)

Voriconazole__NIS_Protocol_A1501103_ Amend I_18June2015_EU PAS Register_Final.pdf (757.44 KB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

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

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To estimate the incidence rate of hepatic disorders, phototoxicity, SCC of the skin, visual disorders and periostitis among adult and paediatric patients receiving voriconazole, particularly with long-term use.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational, population-based study

Study drug and medical condition

Medicinal product name

VFEND

Medical condition to be studied

Candida sepsis

Aspergillus infection

Population studied

Short description of the study population

The study included patients with at least one filled prescription of voriconazole in the Swedish Prescribed Drug Register. The patients were identified from the population-based Swedish National Registers from 2006 to 2021 for the study period of 1 January 2006 to 31 December 2017.

Eligibility criteria:

• Patients with at least one filled prescription of voriconazole in the Swedish Prescribed Drug Register will be included in this study.

• Note: Although the study will include patients with at least one filled prescription of voriconazole to be inclusive for safety reporting purposes, the analysis for the study objective will mainly focus on patients treated with long-term voriconazole use.

Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 years)
- Infants and toddlers (28 days – 23 months)
- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- 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

3660

Study design details

Outcomes

The primary study outcomes are hepatic disorders, phototoxicity, SCC of the skin, periostitis and visual disorders. Secondary outcomes include gastrointestinal disorders, nausea, vomiting, abdominal pain, abdominal discomfort, diarrhea, dyspepsia, flatulence, non-infective gastroenteritis, and death.

Data analysis plan

Descriptive statistics will be performed to describe patient demographic and clinical characteristics.Demographic characteristics include age, sex, geographic region, county of birth, and occupation.Clinical characteristics include co-morbid/underlying conditions, use of voriconazole for approved or non-approved indications, and concomitant medications.Main outcomes (safety events) will be analyzed using a piecewise exponential model that allows separate estimation of the hazard within voriconazole treatment intervals (≤3 months, >3 to ≤6 months, >6 to ≤9 months, >9 to ≤12 months, and > 12 month).The following results will be presented by safety event: • Incidence rates and cumulative incidence rates with corresponding 95% CI, • Number of new events reported during follow-up, • Cumulative person-time at risk, and • Sub-group analyses of incidence rates across various demographic and baseline characteristics(i.e. age group, co-morbid/underlying conditions)when enough data exist

Documents

Study results

A1501103_VFEND PASS FINAL REPORT _EU PAS REGISTER.pdf (735.17 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

The Swedish prescribed drug register

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Drug dispensing/prescription data

Other

Data sources (types), other

Death Register, Population Registers, Medical Charts

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