Evaluation of the effectiveness of additional risk minimisation measures (aRMMs) that aim to reduce the risks of phototoxicity, squamous cell carcinoma (SCC) of the skin and hepatic toxicity in patients receiving voriconazole in the European Union (EU)

First published: 29/07/2015

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10428

Study ID

14677

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Hungary
- [ ] Ireland
- [ ] Italy
- [ ] Netherlands
- [ ] Spain
- [ ] United Kingdom

Study description

The study is a survey of healthcare professionals (HCPs) to evaluate the effectiveness of the additional risk minimisation measures (aRMMs) being implemented across Europe to mitigate the risks associated with voriconazole (Vfend®) (i.e. phototoxicity, SCC of the skin and hepatic toxicity in patients using voriconazole). The evaluation is being conducted in 10 of the 33 countries in the EU where RM tools are being implemented. Specifically, the goals of the study are to: 1) Assess HCPs' awareness of the RM tools, 2) Assess HCPs' utilization of the RM tools, 3). Assess HCPs' knowledge of the risks, 4) Assess whether HCPs' self reported behaviour/practices with respect to minimizing the risks of phototoxicity, SCC of the skin and hepatic toxicity are in accordance with the voriconazole SmPC. The study objectives will be accomplished by means of a cross-sectional survey of all targeted HCPs who received the aRMMs and self-report as prescribers of voriconazole in 10 EU countries. Voriconazole is mainly prescribed by select specialty care physicians (i.e., infectious disease physicians, oncologists, haematologists, solid organ transplant physicians---however the speciality that actually prescribes voriconazole can vary by country). These speciality care physicians in the 10 EU countries will constitute

the study population for the survey. A structured self-administered questionnaire comprised of closed-ended questions or statements with multiple response choices will be used to collect the survey data. The questionnaire will collect data on HCP characteristics in addition to their responses pertaining to the effectiveness of the aRMMs. A sample size of 750 completed surveys is being targeted across 10 countries.

Study status

Finalised

Research institutions and networks

Institutions

United BioSource Corporation (UBC)

Switzerland

First published: 25/04/2013

Last updated: 06/03/2024

Institution | **Non-Pharmaceutical company** | **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Joanna Lem

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/08/2013

Actual: 05/08/2013

Study start date

Planned: 01/09/2015

Actual: 02/09/2015

Data analysis start date

Planned: 02/03/2016

Actual: 02/03/2016

Date of final study report

Planned: 31/05/2016

Actual: 17/05/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A1501102_VFEND aRMM evalution survey PROTOCOL_FINAL REDACTED_7_28_2015_B.pdf(341.59 KB)

A1501102_PROTOCOL AND APPROVAL_NIS_08JULY2015_FINAL_part1.pdf(637.76 KB)

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The overall objective is to evaluate the effectiveness of the additional RMMs being implemented across Europe to mitigate the risks of phototoxicity, SCC of the skin and hepatic toxicity with the use of voriconazole.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J02AC03) voriconazole

voriconazole

Population studied

Short description of the study population

Healthcare professionals that prescribe voriconazole and received the RM tools in the following countries: UK, France, Austria, Ireland, Denmark, Germany, Spain, Italy, Netherlands, and Hungary.

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

332

Study design details

Data analysis plan

Data collected from the survey will be reported as descriptive statistics. Frequency distributions with 95% CIs will be calculated for HCPs' responses to all questions that address the survey objectives. Depending on the sample size, survey data will be stratified by country and medical specialty. In the final analysis of all specialists there will be weighted analysis completed based on HCP speciality.

Documents

Study results

a1501102-report-body_1.pdf(1.41 MB)

Study report

a1501102-abstract.pdf(1.9 MB)

Study, other information

A1501102_PROTOCOL AND APPROVAL_NIS_08JULY2015_FINAL_part2.pdf(1.68 MB)

A1501102_PROTOCOL AND APPROVAL_NIS_08JULY2015_FINAL_part3.pdf(1.16 MB)

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

Cross-sectional survey

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