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 Saudi Arabia

First published: 30/10/2024

Last updated: 30/10/2025

Study Finalised

Administrative details

EU PAS number

EUPAS1000000266

Study ID

1000000266

DARWIN EU® study

No

Study countries

Saudi Arabia

Study description

Pfizer Saudi Limited will conduct a non-interventional, cross-sectional survey of healthcare professionals (HCPs) to evaluate the effectiveness of the aRMMs being implemented across Saudi Arabia to mitigate the risks of phototoxicity, SCC of the skin and hepatic toxicity in patients prescribed voriconazole (Vfend®).

To ensure that the risks are adequately managed, aRMMs in Saudi Arabia have been implemented since Feb 2023. The aRMM material distribution has been started on 05-Feb-2023 and continued until 05-Feb-2024 to the relevant HCPs who may initiate or manage patients on Vfend®.
The RM tools are the HCP Checklist, HCP Question & Answer (Q&A) Brochure and Patient Alert Card. HCPs who the materials are targeting will be invited to participate in the survey.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Primary lead investigator

Hala Sayed

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 29/04/2024

Study start date

Planned: 15/11/2024

Actual: 11/11/2024

Date of final study report
Planned: 30/06/2025

Actual: 26/06/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Saudi Limited 100% Funding

Study protocol

A1501110_Non Interventional Study Protocol (Combined)_V1_16AUG2024_Redacted.pdf (558.23 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Study design:

The data from the HCPs will be collected using a structured self-administered questionnaire to gather evaluation metrics related to the utilization and understanding of RM tool content and messages. In addition, the survey will assess behaviors, including a set of hypothetical scenarios for HCPs.

Main study objective:

The overall objective of the study is to evaluate the effectiveness of the aRMMs being implemented across Saudi Arabia 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

Medicinal product name

VFEND

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

VORICONAZOLE

Anatomical Therapeutic Chemical (ATC) code

(J02AC03) voriconazole

voriconazole

Population studied

Short description of the study population

The target population will include all HCPs who were targeted to receive Vfend® aRMM materials within 12 months preceding the survey in Saudi Arabia (Central, East and North regions). It is important to note that the final survey sample size will depend on HCPs' willingness to participate in the survey.

Estimated number of subjects

10

Study design details

Setting

Given this relatively small pool of HCPs, an empirical sample size of 10 HCPs is proposed.

Participants/ HCPs must meet all of the following criteria to be eligible for inclusion in the survey:
1. Willing/consent to participate in this self-administered survey.
2. Involved in the treatment of at least one patient with voriconazole within the last 12 months.

Participants/ HCPs meeting any of the following criteria will not be included in the survey:
1. Employed in full-time research or hospital administration (i.e., non practicing physicians).
2. Employment by Pfizer Inc or any research organization/vendor contracted by Pfizer to administer the survey.

Outcomes
1. Estimate the proportion of targeted HCPs who acknowledge receiving the tools.
2. Estimate the proportion of targeted HCPs who acknowledge reading and utilizing the tools.
3. Estimate the proportion of targeted HCPs who responds correctly to questions about the risks of phototoxicity, SCC of the skin, and hepatic toxicity.
4. Estimate the proportion of targeted HCPs who provided desirable responses to the practice-related questions and self-declared behavior with regard to strategies to mitigate the risks.

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.

Documents

Study report

A1501110_Non-Interventional Study Report_V1_20JUN2025_Redacted.pdf

(627.65 KB)

Study, other information

A1501110_Non-Interventional Study Report_V2_03OCT2025_Redacted.pdf

(376.25 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

A structured self-administered questionnaire comprised of closed-ended questions or statements with multiple response choices (ie, questions or statements asking the HCPs to choose from a defined list of responses) will be used to collect the survey data.

Data sources (types)

Non-interventional study

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

Not applicable