

# Evaluation of the Potential Association Between Voriconazole Use and Squamous Cell Carcinoma (SCC) of Skin Among Patients With Lung or Lung/Heart Transplants

**First published:** 26/11/2013

**Last updated:** 01/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS5269

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### Study ID

28286

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### DARWIN EU® study

No

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### Study countries

 Australia

 Belgium

-  Canada
  -  France
  -  Germany
  -  Italy
  -  Netherlands
  -  Spain
  -  Switzerland
  -  United States
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### **Study description**

This retrospective cohort study will assess the potential association between voriconazole use and the development of SCC of skin in patients with lung or heart/lung transplant. Patients will be identified from a multicenter, multinational database of lung transplant patients being developed at the University of Toronto, Canada. This database will contain retrospective patient-level data from several lung transplant centers in the EU and North America.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

[University Health Network/University of Toronto](#)

Multiple centres: 14 centres are involved in the study

## Contact details

### Study institution contact

Muhammad Younus [muhammad.younus2@pfizer.com](mailto:muhammad.younus2@pfizer.com)

Study contact

[muhammad.younus2@pfizer.com](mailto:muhammad.younus2@pfizer.com)

### Primary lead investigator

Muhammad Younus

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 25/11/2013

Actual: 25/11/2013

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### Study start date

Planned: 09/12/2013

Actual: 09/12/2013

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### Data analysis start date

Planned: 19/05/2015

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### **Date of final study report**

Planned: 31/12/2015

Actual: 04/12/2015

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

[Voriconazole Study Protocol.pdf](#) (210.87 KB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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### **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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To assess the potential association between voriconazole use and the development of SCC of the skin in patients with lung or heart/lung transplant.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

VFEND

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**Medical condition to be studied**

Lung transplant

## Population studied

### **Short description of the study population**

Patients undergoing Lung Transplant at the study transplant centers between 1 January, 2005 and 31 December, 2008

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### **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)
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### **Special population of interest**

Immunocompromised

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### **Estimated number of subjects**

471

## Study design details

### **Outcomes**

To assess the potential association between voriconazole use and the development of SCC of the skin in patients with lung or heart/lung transplant.

To assess the potential association between voriconazole use and the development of melanoma in patients with lung or heart/lung transplant

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## Data analysis plan

Descriptive statistics will be presented to describe patient characteristics such as age at transplant, sex, race/ethnicity, reasons for transplant, co-morbid conditions and immunosuppressive agents used in the voriconazole exposed and unexposed cohorts. Univariate and multivariate Cox proportional hazard regression analyses will be conducted to assess the association between voriconazole and SCC of the skin.

## Documents

### Study results

[PASS A1501097\\_ Abstract .pdf](#) (160.08 KB)

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### Study report

[PASS A1501097 Study Report.pdf](#) (511.95 KB)

### Study publications

[Hamandi B, Fegbeutel C, Silveira FP, Verschuuren EA, Younus M, Mo J, Yan J, Uss...](#)

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## 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

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### Data sources (types), other

A new database is being developed by the Principal Investigator by compiling patient-level data from several lung transplant centers in EU and North America.

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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### Check stability

Unknown

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### Check logical consistency

Unknown

## Data characterisation

## **Data characterisation conducted**

Unknown