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

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Study Finalised

Administrative details

EU PAS number

EUPAS5269

Study ID

28286

DARWIN EU® study

No

Study countries

Australia

Belgium

- Canada
- France
- Germany
- Italy
- Netherlands
- Spain
- Switzerland
- United States

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.

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

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Study contact

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Primary lead investigator

Muhammad Younus

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/11/2013

Actual: 25/11/2013

Study start date

Planned: 09/12/2013

Actual: 09/12/2013

Data analysis start date

Planned: 19/05/2015

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

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

Data collection methods:

Secondary use of data

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

Medical condition to be studied

Lung transplant

Heart and 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

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)

Special population of interest

Immunocompromised

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

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)

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…

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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown