Impact of withdrawal of fusafungine from the market on the prescribing of alternative treatments in Germany (Fusafungine impact study)

First published: 14/06/2018

Last updated: 12/03/2020

Study Finalised

Administrative details

EU PAS number

EUPAS24430

Study ID

34098

DARWIN EU® study

No

Study countries

Germany

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

Karin Hedenmalm karin.hedenmalm@ema.europa.eu

Study contact

karin.hedenmalm@ema.europa.eu

Primary lead investigator

Karin Hedenmalm

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/12/2015

Actual: 18/12/2015

Study start date

Planned: 15/08/2017

Actual: 15/08/2017

Data analysis start date

Planned: 15/08/2017

Actual: 15/08/2017

Date of final study report

Planned: 30/06/2018

Actual: 01/12/2019

Sources of funding

- EMA

Study protocol

PASS_protocol.pdf (62.58 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To study changes in prescribing of alternative treatments for upper respiratory airways disease after the withdrawal of fusafungine

Study drug and medical condition

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

FUSAFUNGINE

Medical condition to be studied

Upper respiratory tract infection

Upper respiratory tract inflammation

Population studied

Short description of the study population

General Practioners, specialists in internal medicine and other specialist physicians in computerized practices throughout Germany since 1992

Age groups

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

10000

Study design details

Data analysis plan

An interrupted time series regression analysis will be used to evaluate statistically the effect of the withdrawal on treatment pathways in patients with selected URAD, comparing the four quarters after the withdrawal with the 12 previous quarters. This will be done using linear regression. Included fusafungine-prescribing practices will be compared to practices with no fusafungine prescribing.

Documents

Study publications

Hedenmalm K, Kurz X, Morales D. Effect of withdrawal of fusafungine from the ma…

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

IQVIA Disease Analyzer Germany

Data sources (types)

Electronic healthcare records (EHR)

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