A description of the management of invasive fungal infections with oral posaconazole maintenance treatment following intravenous antifungal regimens in routine UK clinical practice (MAINTAIN)

First published: 25/04/2014

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/6411

EU PAS number

EUPAS6410

Study ID

6411

DARWIN EU® study

No

Study countries

United Kingdom

Study description

A multi-centre, retrospective observational study to describe the current management of patients prescribed oral posaconazole as continuation therapy following previous intravenous (IV) antifungal treatment. Primary objective: To describe the population of patients prescribed oral posaconazole following previous IV antifungal treatment for possible, probable or proven invasive fungal infection (IFI). Secondary objectives: to describe, antifungal prophylaxis medications prior to treatment for IFI, IV antifungal treatments prior to posaconazole, dose/duration of posaconazole treatment, numbers and types of tests/investigations and NHS attendances during IV antifungal and posaconazole treatment, clinical outcomes at 12 months post-initiation of IV antifungal treatment. The study will involve retrospective collection of data from the medical records of patients (aged ≥18) prescribed oral posaconazole continuation treatment on/after 1st Jan 2010, following prior IV antifungal treatment.

Study status

Ongoing

Research institutions and networks

Institutions

Merck & Co.

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Institution

Birmingham Centre for Clinical Haematology Birmingham, UK, Leicester Royal Infirmary Leicester, UK, Centre for Clinical Haematology, Nottingham University Hospital Nottingham, UK

Contact details

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Primary lead investigator

Charles Craddock

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 03/12/2012

Study start date
Actual: 20/01/2014

Data analysis start date
Planned: 30/06/2014

Date of final study report
Planned: 31/08/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

To describe the population of patients who receive oral posaconazole following previous intravenous (IV) antifungal treatment for possible, probable or proven invasive fungal infection.

Study drug and medical condition

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

POSACONAZOLE

Medical condition to be studied

Fungal infection

Population studied

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

30

Study design details

Outcomes

Demographic/disease characteristics including, Gender, age, ethnicity, weight, height and BMI, Comorbidities, primary diagnosis inc transplant type if relevant, Graft vs host disease (GVHD) prophylaxis, treatment of acute GVHD if relevant, prior and current chemotherapy regimens, reasons for initiating initial IV antifungal agent, probable/possible/proven IFI, type of fungal infection. Antifungal prophylaxis regimens prior to starting IFI treatment, IV antifungal regimens prior to posaconazole initiation, posaconazole dose & duration, outcomes at 12 months post-initiation of IV antifungal treatment (% patients with resolution of infection according to CT, % surviving, % with no further IV antifungal treatment), resource use (tests & hospital attendances) during IFI treatment

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Data analysis plan

Analyses will be descriptive in nature. Both distributions and descriptive statistics of both central tendency (medians and arithmetic or geometric means) and dispersion (standard deviation, interquartile range) will be presented for quantitative variables. Nominal variables will be described with frequencies, percentages and modes, while ordinal variables will also have medians and interquartile ranges described.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Retrospective data collection from patients’ routine hospital medical records

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