Prospective, multi-country, observational registry to collect clinical

First published: 12/12/2017

Last updated: 03/10/2022

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/46710

EU PAS number

EUPAS21731

Study ID

46710

DARWIN EU® study

No

Study countries

Austria

Croatia

Czechia

France

Germany

Italy

Netherlands

Portugal

Spain

Sweden

Study description

To collect clinical information in patients with Cushing’s syndrome (CS) exposed to ketoconazole, to assess drug utilization patterns and to document the safety, and effectiveness of ketoconazole. The primary objective is to collect and assess safety data with a particular focus on the important identified risks of hepatotoxicity and QT prolongation. The secondary objectives are to collect and assess other safety data, to evaluate the effectiveness and drug utilization patterns of ketoconazole.

Study status

Ongoing

Research institution and networks

Institutions

HRA Pharma Rare Diseases

First published: 01/02/2024

Last updated: 01/02/2024

Institution

University of Bordeaux

France

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution

University Hospital Centre Zagreb (KBC Zagreb)

Croatia

First published: 23/07/2013

Last updated: 20/08/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau – IIB Sant Pau

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Charité-Universitätsmedizin

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Erasmus Medical Centre Rotterdam

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Hôpital de la Conception Marseille Centre Hospitalier Universitaire de Bordeaux, Hôpital Bicêtre Paris University Hospital Zagreb, Hôpital Universitaire de Grenoble Dr Sahlgrenska University Hospital Goteborg, Hôpital Cochin Paris Centro Hospitalar de Lisboa Ocidental, Institut de Recerca de la Santa Creu i Sant Pau Barcelona Hospitalar Universitário de Coimbra, Hospital clinic Barcelona Centro Hospitalar Universitário do Porto, Hospital Universitario de La Ribera University Hospital in Prague, Hospital General

Universitario Gregorio MaranonMadrid Charité Universitatsmedizin Berlin, Hospital Universitario de Albacete Klinikum der Universitat München, Erasmus University Medical Center Rotterdam MEDICOVER Oldenburg MVZ- Oldenburg

Networks

ERCUSYN

Contact details

Study institution contact

Martine Bostnavaron

Study contact

m.bostnavaron@HRA-PHARMA.COM

Primary lead investigator

Myriam Bou Nader

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 29/12/2017

Actual: 31/07/2018

Study start date
Planned: 01/03/2018

Actual: 01/11/2018

Date of interim report, if expected
Planned: 01/11/2018

Actual: 29/10/2018

Date of final study report
Planned: 01/03/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

HRA Pharma Rare Diseases

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Regulatory procedure number

EMEA/H/C/003906/ANX/002,EMEA/H/C/PSP/0040

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The primary objective is to collect and assess safety data with a particular focus on the important identified risks of hepatotoxicity and QT prolongation.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective Observational study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J02AB02) ketoconazole

ketoconazole

Medical condition to be studied

Cushing's syndrome

Population studied

Age groups

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

200

Study design details

Outcomes

Incidence of hepatotoxicity in case of liver enzymes increase and time to onset since ketoconazole initiation and time to recovery. Incidence of QTc prolongation and time to onset since ketoconazole initiation and time to recovery. The secondary endpoints for secondary objectives are the following: - Other Safety and Tolerability endpoints - Drug utilisation pattern endpoints - Effectiveness endpoints - QoL endpoint

---

Data analysis plan

Details of the data analysis will be provided in a Statistical Analysis Plan (SAP).

Data management

Data sources

Data sources (types)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection

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