

Prospective, multi-country, observational registry to collect clinical

First published: 12/12/2017

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Study

Ongoing

Administrative details

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 institutions and networks

Institutions

[Esteve Pharmaceuticals, S.A.](#)

[Charité-Universitätsmedizin](#)

First published: 01/02/2024

Last updated: 01/02/2024

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

University of Bordeaux

 France

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Educational Institution

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

Erasmus Medical Centre Rotterdam

First published: 01/02/2024

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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 Maranon Madrid Charité
Universitätsmedizin Berlin, Hospital Universitario
de Albacete Klinikum der Universität München,

Erasmus University Medical Center Rotterdam
MEDICOVER Oldenburg MVZ- Oldenburg

Networks

ERCUSYN

Contact details

Study institution contact

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Study contact

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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

EMA/H/C/003906/ANX/002,EMA/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

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)

[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