A 5-year enhanced Pharmacovigilance surveillance initiative to survey and characterise spontaneous occurrence and experience of ketoacidotic events in patients treated with Empagliflozin –containing products

First published: 20/06/2018

Last updated: 02/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS21696

Study ID

27897

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Aruba
- [ ] Australia
- [ ] Austria
- [ ] Bahamas
- [ ] Bahrain
- [ ] Barbados
- [ ] Belarus
- [ ] Belgium
- [ ] Bermuda
- [ ] Bosnia and Herzegovina
- [ ] Botswana
- [ ] Brazil
- [ ] Brunei Darussalam
- [ ] Bulgaria
- [ ] Canada
- [ ] Cayman Islands
- [ ] Chile
- [ ] China
- [ ] Colombia
- [ ] Costa Rica
- [ ] Croatia
- [ ] Cuba
- [ ] Cyprus
- [ ] Czechia
- [ ] Denmark
- [ ] Dominican Republic
- [ ] Ecuador
- [ ] Egypt

- [ ] El Salvador
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Guatemala
- [ ] Honduras
- [ ] Hong Kong
- [ ] Hungary
- [ ] Iceland
- [ ] India
- [ ] Indonesia
- [ ] Ireland
- [ ] Israel
- [ ] Italy
- [ ] Jamaica
- [ ] Japan
- [ ] Jordan
- [ ] Kazakhstan
- [ ] Korea, Republic of
- [ ] Kuwait
- [ ] Latvia
- [ ] Lebanon
- [ ] Liechtenstein
- [ ] Lithuania
- [ ] Luxembourg
- [ ] Macau
- [ ] Malaysia
- [ ] Malta

- [ ] Mexico
- [ ] Morocco
- [ ] Namibia
- [ ] Netherlands
- [ ] Netherlands Antilles
- [ ] New Zealand
- [ ] North Macedonia
- [ ] Norway
- [ ] Panama
- [ ] Paraguay
- [ ] Peru
- [ ] Philippines
- [ ] Poland
- [ ] Portugal
- [ ] Qatar
- [ ] Romania
- [ ] Russian Federation
- [ ] Saudi Arabia
- [ ] Serbia
- [ ] Singapore
- [ ] Slovakia
- [ ] Slovenia
- [ ] South Africa
- [ ] Spain
- [ ] Sri Lanka
- [ ] Sweden
- [ ] Switzerland
- [ ] Taiwan
- [ ] Thailand
- [ ] Türkiye

- [ ] Ukraine
- [ ] United Arab Emirates
- [ ] United Kingdom
- [ ] United States
- [ ] Uruguay
- [ ] Viet Nam

Study description

The rationale behind this initiative is to perform surveillance of spontaneous adverse event reports from post-marketed experience of ketoacidosis as well as:1) To better describe characteristics of patients developing KA under empagliflozin treatment.2) To characterise potential predisposing factors in patients developing KA under empagliflozin treatment.3) To characterize the clinical presentation of KA in patients taking empagliflozin treatment.

Study status

Ongoing

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Fernando Solimando

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/06/2016

Actual: 30/06/2016

Study start date

Planned: 01/09/2016

Actual: 01/09/2016

Data analysis start date

Planned: 01/09/2021

Date of interim report, if expected

Planned: 31/12/2017

Actual: 03/01/2019

Date of final study report

Planned: 31/12/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

1245.146 FINAL PROTOCOL VER 01 28 JUN 2016.pdf(263.45 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)

Other study registration identification numbers and links

1245.146

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Main study objective:

To assess and characterize a potential patient population at risk for Ketoacidosis (KA), characterize the circumstances behind predisposing factors, course and treatment of KA in patients undergoing empagliflozin treatment.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Enhanced Pharmacovigilance Initiative

Study drug and medical condition

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

EMPAGLIFLOZIN

LINAGLIPTIN

METFORMIN

Anatomical Therapeutic Chemical (ATC) code

(A10BK) Sodium-glucose co-transporter 2 (SGLT2) inhibitors

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Medical condition to be studied

Type 2 diabetes mellitus

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)

Special population of interest

Renal impaired

Hepatic impaired

Estimated number of subjects

3000

Study design details

Outcomes

To better describe characteristics of patients developing Ketoacidosis (KA) under empagliflozin treatment, 1) To characterize potential predisposing factors in patients developing Ketoacidosis (KA) under empagliflozin treatment.2) To

characterize the clinical presentation of KA in patients taking empagliflozin treatment

Data analysis plan

Analyses will be based on descriptive statistics of the available sample provided by reports of Ketoacidosis (KA) and KA-related events as described above and defined by Narrow Scope KA Boehringer Ingelheim (BI) Customised Medical Dictionary for Regulatory Activities (MedDRA) Query (BIcMQ) in the BI Safety Database. The list of preferred terms will be updated with each MedDRA version update, and the final analysis will use the MedDRA version valid at the moment data collection period is finalised. An Additional sensitivity analysis based on the broad scope BIcMQ is also intended to be performed.

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)

Spontaneous reports of suspected adverse drug reactions

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