Specific Clinical Experience Investigation for long-term use of Bydureon subcutaneous injection 2 mg and Bydureon SC Pen 2 mg (PMS Bydureon Long Term Use SCEI)

First published: 18/04/2017

Last updated: 14/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/37460

EU PAS number

EUPAS18608

Study ID

37460

DARWIN EU® study

No

Study countries

Japan

Study description

To confirm the safety and efficacy of Bydureon (hereinafter referred to as Bydureon) in long-term use in Japanese patients with type 2 diabetes mellitus under actual drug use.1.Primary Objective To confirm the safety profile in Japanese patients with type 2 diabetes mellitus receiving Bydureon under daily practices.2.Secondary objective As the secondary objective of this S-CEI, the following items are to be investigated.Frequencies of AEs related to cardiovascular events, hypoglycaemia, digestive symptoms, and injection site reaction.Development of pancreatitis, renal impairment (especially acute renal failure), hypersensitivity reaction, and malignant tumour (especially thyroid tumour and pancreatic malignancy)Safety in patients with mild or moderate renal impairmentChanges of weight, blood pressure, pulse rate, fasting blood sugar, fasting insulin, HbA1c, and blood lipidsBydureon administration under daily practices focusing on the patient's demographics and clinical characteristics of diabetes mellitus (duration of diabetes mellitus, treatment duration, complications, Bydureon administration, etc)Anti-exenatide antibody titer in AE cases (hypersensitivity, loss of control of blood sugar).

Study status

Finalised

Research institutions and networks

Institutions

AstraZeneca

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 366 centres are involved in the study

Contact details

Study institution contact

Inoue Maki

Study contact

information.center@astrazeneca.com

Primary lead investigator

Kenji Nakamura

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 13/02/2013

Actual: 13/02/2013

Study start date
Planned: 01/10/2013

Actual: 18/10/2013

Data analysis start date
Planned: 01/06/2020

Actual: 02/12/2019

Date of final study report
Planned: 31/08/2020

Actual: 01/07/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astrazeneca K.K.

Study protocol

D5551C00001_BD_11-Dec-2014_ProtocolRedacted.pdf(117.52 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

D5551C00001

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

Safety study (incl. comparative)

If ‘other’, further details on the scope of the study

To confirm efficacy of Bydureon (hereinafter referred to as Bydureon) in long-term use in Japanese patients with type 2 diabetes mellitus under actual drug use.

Data collection methods:

Primary data collection

Main study objective:

To confirm the safety and efficacy of Bydureon (hereinafter referred to as Bydureon) in long-term use in Japanese patients with type 2 diabetes mellitus under actual drug use.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-series, Clinical Experience Investigation based on Japanese regulation

Study drug and medical condition

Name of medicine

BYDUREON

Population studied

Short description of the study population

The patients with type 2 diabetes mellitus who will be given Bydureon for the first time and who inadequately respond to sulfonylurea, biuguanides, and/or thiazolidines (monotherapy or combination use) in addition to diet and exercise.

The patients who meet the following conditions:

- The patients with type 2 diabetes mellitus who inadequately respond to sulfonylurea, biuguanides, and/or thiazolidines (monotherapy or combination use) in addition to diet and exercise.

The patient who will receive Bydureon in any of the following combinations:

- Bydureon + sulfonylurea
- Bydureon + biguanides
- Bydureon + thiazolidines
- Bydureon + sulfonylurea + biguanides
- Bydureon + sulfonylurea + thiazolidines
- Bydureon + biguanides + thiazolidines

- No past history of hypersensitivity to the components of Bydureon.
- Not the patient with diabetic ketoacidosis, diabetic coma/precoma, and/or type 1 diabetes mellitus.
- Bydureon will not be administered to the patient in an emergency situation such as severe infection and operation.
- Not the patient with severe renal impairment, including those receiving dialysis.

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)

Special population of interest

Hepatic impaired

Immunocompromised

Other

Pregnant women

Renal impaired

Special population of interest, other

Type 2 diabetes mellitus patients

Estimated number of subjects

1100

Study design details

Outcomes

To confirm the safety profile in Japanese patients with type 2 diabetes mellitus receiving Bydureon under daily practices. Frequencies of AEs related to cardiovascular events, hypoglycaemia, digestive symptoms, and injection site reaction, pancreatitis, renal impairment (especially acute renal failure), hypersensitivity reaction, and malignant tumour (especially thyroid tumour and pancreatic malignancy). Safety in patients with mild or moderate renal impairment.

Data analysis plan

risk estimation, measures of risk

Documents

Study results

D5551C00001_redacted_CSR_Synopsis.pdf(152.01 KB)

Data management

Data sources

Data sources (types)

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