Exenatide (Byetta subcutaneous injection) Specific Clinical Experience Investigation for long-term use (PMS Byetta Long Term Use SCEI)

First published: 19/07/2017

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS19606

Study ID

37369

DARWIN EU® study

No

Study countries

☐ Japan

Study description

To confirm the safety and efficacy of Byetta subcutaneous injection (hereinafter referred to as Byetta) in long-term use under actual drug use. 1.Primary Objective To confirm development of adverse events with administration of Byetta. Especially, development of acute pancreatitis and cardiovascular related events (MACE:Major Adverse Cardiovascular Events) should be focused on.2.Secondary objective As the secondary objective of this investigation, the following items are to be investigated.- The safety and efficacy in patients with renal impairment - ADR development related to hypoglycaemia, digestive symptoms, and malignant neoplasm- Variation of HbA1c from the baseline- Changes of weight, blood pressure, and blood lipid- Change of satisfaction level with diabetes treatment- Expression of exenatide antibody in cases of hypersensitivity

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Study status

Finalised

Research institutions and networks

Institutions

AstraZeneca

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Institution

Multiple centres: 616 centres are involved in the study

Contact details

Study institution contact

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Study contact

ClinicalTrialTransparency@astrazeneca.com

Primary lead investigator

Nakamura Kenji

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 13/12/2010

Actual: 13/12/2010

Study start date

Planned: 01/02/2011

Actual: 04/02/2011

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

D5550C00001_EUPAS19606_Protocol_ENCePP.pdf(114.99 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

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 the efficacy of Byetta 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 Byetta 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

BYETTA

Population studied

Short description of the study population

Type II diabetes mellitus patients

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

Pregnant women

Renal impaired

Estimated number of subjects

2950

Study design details

Outcomes

To confirm the safety profile in Japanese patients with type 2 diabetes mellitus receiving Byetta 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

D5550C00001_redacted_CSR_synopsis.pdf(148.46 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