AN OBSERVATIONAL POST-AUTHORIZATION MODIFIED PRESCRIPTION-EVENT MONITORING SAFETY STUDY TO MONITOR THE SAFETY AND UTILIZATION OF EXENATIDE ONCE WEEKLY (BYDUREON®) IN THE PRIMARY CARE SETTING IN ENGLAND

First published: 21/01/2014

Last updated: 16/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS5599

Study ID

32333

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This post-marketing Modified Prescription-Event Monitoring (M-PEM) safety study of exenatide (Bydureon®) is to be carried out as part of the Risk Management Plan required by the Committee for Medicinal Products for Human Use (CHMP) to further investigate the safety profile of Bydureon® in clinical practice. The aim of this study is to proactively capture safety and drug utilisation data in the post-marketing phase of license approval of Bydureon® as prescribed to patients by general practitioners in England. This M-PEM study will enable the systematic collection and reporting of drug utilisation and safety data on patients newly initiated on treatment with exenatide once weekly in the primary care setting. The study aims to collect exposure and outcome data for a cohort of approximately 5000 evaluable patients

Study status

Finalised

Research institutions and networks

Institutions

Drug Safety Research Unit (DSRU)

United Kingdom

First published: 10/11/2021

Last updated: 09/01/2026

Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Saad Shakir

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 23/02/2012

Study start date

Planned: 02/09/2011

Actual: 01/09/2011

Data analysis start date

Planned: 02/04/2018

Actual: 01/05/2018

Date of interim report, if expected

Planned: 01/12/2015

Actual: 01/12/2015

Date of final study report

Planned: 01/11/2018

Actual: 21/12/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly &Co (36%), AstraZeneca (64%)

Study protocol

Exenatide_M_PEM_full_protocol_FINAL_14_11_14_v3.2_ EUPAS.pdf (722.7 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)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To provide timely information to quantify the incidence rate of the important identified risk of acute pancreatitis in the first 12 months after starting treatment.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Modified PrescriptionEvent Monitoring

Study drug and medical condition

Medicinal product name

BYDUREON

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

Type 2 diabetes mellitus patients newly initiated on treatment with exenatide once weekly in the primary care setting.
Patients, for whom a study questionnaire containing useful information has been returned, were eligible for inclusion in the evaluable patient study cohort.

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

Other

Special population of interest, other

Type 2 diabetes mellitus patients

Estimated number of subjects

5000

Study design details

Outcomes

The incidence rate of the important identified risk of acute pancreatitis in the first 12 months after starting treatment, 1. The baseline health profile of patients on treatment with exenatide in the primary care setting, the treatment they received, and by whom2. The risk profile of events reported in the 12 month observation period in the overall cohort and in special populations (arising from contraindications, precautions etc.)

Data analysis plan

PEM methodology provides a numerator (the number of reports of an event) and a denominator (the number of patient-months at risk), both collected within a known time frame. This allows for the calculation of risk (percent of total valid cohort exposed) and incidence densities (ID, person-time incidence rates) for each event. Such analyses will be performed using ‘Higher-level’ event terms from the MedDRA dictionary.In addition, the incidence rate of acute pancreatitis will be explored in exenatide naïve and switcher patients by estimating the hazard rate of this event over time. The null hypothesis that the hazard rate of acute pancreatitis in patients exenatide will be constant during the 12 month exposure period following the start of treatment will be tested by fitting parametric time to event models (e.g. Weibull).Descriptive summary statistics will also be employed to present such as demographic data.

Documents

Study results

Exenatide M-PEM Final Report_v3.0 ENCePP_Redacted.pdf (4.2 MB)

Data management

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)

Other

Data sources (types), other

Prescription event monitoring

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