Healthcare Professional and Patient Surveys to Assess the Effectiveness of Risk Minimisation Measures for Concentrated Insulin Lispro (Humalog 200 units/ml KwikPen; Liprolog 200 units/ml KwikPen) (F3Z-MC-B019)

First published: 10/05/2016

Last updated: 26/09/2017

Study | Finalised

Administrative details

EU PAS number

EUPAS13422

Study ID

21063

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Sweden

Study description

This study aims to evaluate the impact of the additional risk minimisation measures on healthcare professional and patient understanding and behaviour regarding the risk of hypoglycaemia and/or hyperglycaemia due to medication errors associated with administration of Humalog KwikPen 200 units/ml. The study will be conducted in France, Germany, and Sweden within 12-18 months of product launch.

Study status

Finalised

Research institutions and networks

Institutions

United BioSource Corporation (UBC)

- [ ] Switzerland

First published: 25/04/2013

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ayad Ali

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/10/2014

Actual: 31/10/2014

Study start date

Planned: 30/06/2016

Actual: 16/05/2016

Date of final study report

Planned: 30/06/2017

Actual: 29/03/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

F3Z-MC-B019_EU-PAS-Registered.pdf (494.57 KB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

This primary study objective is to evaluate the impact of the risk minimisation measures on HCP and patient understanding regarding the risk of hypoglycaemia and/or hyperglycaemia due to medication errors associated with administration of Humalog KwikPen 200 units/ml as communicated through the risk minimisation measures.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Survey Design

Study drug and medical condition

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

INSULIN LISPRO

Population studied

Short description of the study population

HCPs involved in the treatment and management of patients with diabetes who are aware of the insulin product Humalog 200 units/ml KwikPen were eligible. Patients who are 18 years or older, have diabetes and have been prescribed Humalog 200 units/ml KwikPen were eligible.
HCPs and patients in the United Kingdom (UK, if product uptake does not allow for participation, another comparable EU country will be selected), Germany, and one additional EU country, to be determined based on product launch and market uptake.

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

Other

Special population of interest, other

Diabetes mellitus patients

Estimated number of subjects

560

Study design details

Outcomes

The risk minimisation tools will be considered effective if the majority of respondents demonstrate they are aware of the key risks communicated.

Data analysis plan

Data collected from the survey will be reported as descriptive statistics. Frequency distributions with 95% CIs will be calculated for respondent responses to all questions that address the survey objectives.In addition to the overall analysis, survey data will be analysed to determine if there are any differences by country and, for HCPs, medical specialty.

Documents

Study results

F3Z-MC-B019_Final_Report_EUPAS_Registered.pdf (1020.41 KB)

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)

Other

Data sources (types), other

Cross-Sectional Survey, involving primary 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