Healthcare Professional and Patient Surveys to Assess the Effectiveness of Risk Minimization Measures for Concentrated Insulin Lispro (Humalog 200 units/mL KwikPen) (F3Z-MC-B020)

First published: 16/08/2016

Last updated: 18/08/2017

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/20643

EU PAS number
EUPAS14789

Study ID
20643

DARWIN EU® study
No

Study countries
United States

Study description
This study aims to evaluate the impact of the additional risk minimization measures on healthcare professional and patient understanding and behavior regarding the risk of hypoglycemia and/or hyperglycemia due to medication errors associated with administration of Humalog KwikPen 200 units/ml. The study will be conducted in the United States within 18 months of product launch.

Study status
Ongoing

Research institution 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

Study start date
Planned:
30/08/2016
Actual:
15/08/2016

Date of final study report

Planned:
30/01/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

F3Z-MC-B020_EU-PAS-Registered.pdf(303.88 KB)

Regulatory

Was the study required by a regulatory body?
No

Is the study required by a Risk Management Plan (RMP)?
Non-EU RMP only

Methodological aspects

Study type

Study type list

Study type:
Non-interventional study

Scope of the study:
Other

If 'other', further details on the scope of the study
Evaluation of the Effectiveness of a Risk Minimization Plan

Main study objective:
This primary study objective is to evaluate the impact of the risk minimization measures on HCP and patient understanding regarding the risk of hypoglycemia and/or hyperglycemia due to medication errors associated with administration of Humalog KwikPen 200 units/ml as communicated through the risk minimization 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

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)

Estimated number of subjects
560

Study design details

Outcomes
The risk minimization 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 analyzed to determine if there are any differences for HCPs and medical specialty.

Data management

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