Healthcare Professional Survey to Assess the Effectiveness of Additional Risk Minimization Measures for Prescribing and Administration of Concentrated Insulin Human (Humulin R U-500 vial) Using the Dedicated U-500 Insulin Syringe (B5K-MC-B013)

First published: 09/04/2018

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Study Planned

Administrative details

EU PAS number

EUPAS23516

Study ID

23544

DARWIN EU® study

No

Study countries

United States

Study description

This study aims to evaluate the impact of the Dear Health Care Provider letter on prescriber understanding about the risk of potential dosing errors associated with the use and administration of Humulin R U-500 vial using the dedicated U-500 insulin syringe.

Study status

Planned

Research institutions and networks

Institutions

Covance

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Institution

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: 30/11/2016

Study start date
Planned: 31/01/2018

Date of final study report
Planned: 30/04/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

B5K-MC-B013_Registered.pdf(579.65 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:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The primary study objective is to evaluate the impact of the Dear Healthcare Professional letter on prescriber understanding about the risk of potential dosing errors associated with the use and administration of Humulin R U-500 vial using the dedicated U-500 insulin syringe.

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 HUMAN

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

200

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

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