Protocol for the Effectiveness Check of the Awareness and Knowledge of Educational Materials for the Eligard Risk Minimization Program

First published: 23/04/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS9553

Study ID

20725

DARWIN EU® study

No

Study countries

Austria

Belgium

France

Germany

Hungary

Italy

Poland

Spain

Study description

Periodic multi-country surveys of targeted HCPs will be conducted to measure awareness of the Dear Healthcare Provider Communication (DHPC) and other educational materials as well as knowledge of lack of efficacy that may occur with improper reconstitution of Eligard®/Depo-Eligard®. The surveys will be sent to a random sample of individuals receiving the DHPC, stratified by target group. To be included in the analysis of survey responses, respondents must perform one of the following activities as indicated by their survey responses: reconstitute Eligard®/Depo-Eligard® for use in patients, administer Eligard®/Depo-Eligard® to patients, or dispense the medication to patients or healthcare professionals. The survey instrument will be a structured, closed-answer questionnaire of pertinent provider information and key elements relating to the reconstitution of Eligard®/Depo-Eligard®.

Study status

Finalised

Research institutions and networks

Institutions

GfK Health

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nimke David

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/05/2015

Actual: 19/06/2015

Study start date

Planned: 01/06/2015

Actual: 14/10/2015

Date of final study report

Planned: 30/09/2015

Actual: 30/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas Pharma

Study protocol

ELIGARD_PASS_FINALDRAFT_20141216_V1.pdf (96.89 KB)

ELIGARD_7015-MA-3019_v1_1.pdf (1.16 MB)

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

1) To measure the awareness of and participation in the Eligard®/Depo-Eligard® RM activities addressing the potential risk of lack of clinical efficacy due to incorrect reconstitution of the product2) To measure HCP knowledge of a potential risk of lack of efficacy due to incorrect reconstitution process of Eligard®/Depo-Eligard®.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L02AE02) leuprorelin

leuprorelin

Population studied

Short description of the study population

Groups of health care professionals (HCPs) receiving Dear Healthcare Provider Communication (DHPC) who typically reconstitute and/or administer and/or dispense Eligard®/Depo-Eligard® to patients or healthcare professionals.

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

0

Study design details

Data analysis plan

Process Indicators -- Percentage of respondents that recall: receiving the DHPC, reading the DHPC. Percentage of respondents that recall: receiving additional educational materials, reading or viewing additional educational materials, awareness of additional RM activities, participating in additional RM activities. Outcome Indicators -- Overall knowledge level of each target group, calculated as the mean of individual knowledge scores in that group, The percentage of correct responses for each knowledge question for each target group.

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

The study is a cross-sectional survey of healthcare providers.

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

Unknown