Evaluation of the Effectiveness of Risk Minimisation Measures: A Survey among Health Care Professionals to Assess their Knowledge and Attitudes on Prescribing Conditions of Instanyl® in France and the Netherlands

First published: 16/06/2015

Last updated: 29/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/16237

EU PAS number

EUPAS9924

Study ID

16237

DARWIN EU® study

No

Study countries

☐ France

☐ Netherlands

Study description

A survey of prescribers of Instanyl in France and Netherlands to assess the effectiveness of education materials on safe use of Instanyl.

Study status

Finalised

Research institutions and networks

Institutions

Real World Evidence Solutions, IMS Health

☐ France

First published: 06/09/2011

Last updated: 20/08/2024

Institution | Other

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Massoud Toussi

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/03/2015

Actual: 01/03/2015

Study start date
Planned: 01/04/2015

Actual: 01/04/2015

Data analysis start date
Planned: 01/10/2015

Date of final study report
Planned: 01/03/2016

Actual: 16/11/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda Development Centre Europe

Study protocol

Instanyl-5001- Protocol revised-FINAL-2015-02-06-V3 .pdf(928.64 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:

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:

The objective of the survey is to measure the proportion of targeted physicians who received, understood and followed the safety information about Instanyl® provided in the updated educational materials.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Non-interventional survey

Study drug and medical condition

Name of medicine

INSTANYL

Medical condition to be studied

Cancer pain

Population studied

Short description of the study population

Physicians prescribers, or potential prescribers, of Instanyl® who are targeted for the educational materials.

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

267

Study design details

Data analysis plan

Continuous variables will be described by the number of valid cases and missing data, mean, standard deviation, median, Q1, Q3, minimum, and maximum. No missing data will be replaced. Categorical variables will be described as the total number and relative percentage per category. Confidence intervals of 95% will be calculated when relevant.Calculations will first be performed on raw data per specialty, and weighted according to the real proportion of targeted physicians in each country to accurately reflect the population the survey seeks to measure. Possible selection bias will be assessed by comparing the distributions of available characteristics (e.g. region, age, gender, type of practice and specialty) between respondent and non-respondent physicians.

Documents

Study results

Instanyl-5001 Study Report 24 Apr 2016.pdf(3.02 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based 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

Unknown