Instanyl-5002: Assessment of the Effectiveness of Updated Educational Materials on Prescribers' Knowledge and Behavior with Respect to Risks Associated with INSTANYL® Off-Label Use

First published: 25/06/2021

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS41308

Study ID

50156

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Netherlands

Poland

Study description

The purpose of the Instanyl study is to learn how much doctors know and understand about Instanyl® before and after they receive updated educational information, including the risks of its unapproved use. In this study, the doctors will complete two surveys: one three months before they receive the updated educational information, and one about six months after they receive this information. They will answer questions about their prescribing behavior plus their knowledge of Instanyl® including any risks.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

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Institution

Contact details

Study institution contact

Study Contact Takeda trialdisclosures@takeda.com

Study contact

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Primary lead investigator

Study Contact Takeda

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 05/01/2020

Study start date

Planned: 01/02/2022

Actual: 18/02/2022

Data analysis start date

Planned: 01/04/2023

Date of interim report, if expected

Actual: 19/09/2022

Date of final study report

Planned: 30/09/2023

Actual: 20/09/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

Instanyl-5002_PASS_Protocol-V2-Redacted.pdf(1.01 MB)

Instanyl-5002_PASS Protocol v3.0_Amendment v1.0_CLEAN_FINAL_Redacted_17JUL2023.pdf(2.88 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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

Primary objective of the study is to assess prescribers’ awareness of the updated EMs, changes in prescribers’ knowledge and understanding of the key information contained in the updated EMs, changes in prescribers’ self-reported behavior in prescribing, the reasons for off-label prescription, and to assess whether prescribers are fully aware of patients at risk of misuse and addiction.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

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

FENTANYL

Medical condition to be studied

Cancer pain

Population studied

Short description of the study population

A survey of physicians prescribed Instanyl® in France, the Netherlands and Poland.

Inclusion Criteria:

- Specialists of any of those medical specialties targeted for the EMs as agreed with each national competent authority. The foreseen specialties include the following (subject to changes after the EM distribution plan is completed and agreed with national competent authorities):

o Oncologists and oncoradiologists;

o Anaesthesiologists;

o Pain management prescribers;

o Palliative care prescribers;

o Internal medicine prescribers;

o General practitioners (GPs);

o Other specialties may be locally included such as hematology. Current and potential prescribers may vary between country; thus, some countries may have modified lists of target specialties.

- Physicians who have prescribed Instanyl® in the past 12 months (pre-EM survey) or since the updated EMs (post-EM survey) and who intend to prescribe Instanyl® in the following months after each survey.

Exclusion criteria

1. Physicians who may have a conflict of interest (i.e., prescribers employed by regulatory bodies, pharmaceutical industries);
2. Inactive or retired prescribers;
3. Physicians who did not prescribe Instanyl® in the past 12 months (pre-EM survey) or since the updated EMs are distributed (post-EM survey) and do not foresee treating a patient with Instanyl® in the following 12 months, regardless of whether they have prescribed Instanyl® before.

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

536

Study design details

Outcomes

Primary outcomes include changes in prescribers' awareness, knowledge and understanding of key safety information, self-reported behavior and reasons for off-label prescription before and after updated EMs.

Data analysis plan

Descriptive statistics method will be presented. Continuous variables will be described by the number of valid cases, mean, standard deviation, and median first quartile-third quartile (Q1, -Q3,), and minimum and maximum. A 2-sided

95% CI of mean will be presented for success criteria, when relevant. Categorical variables will be described as the total number and relative percentage per category. A 2-sided 95% confidence interval (CI) of percentages will be presented for success criteria. Results will be presented overall per country and specialty, at the specialty level (all countries), and at the country level (all specialties), for each survey.

Documents

Study results

Instanyl-5002-clinical-study-report-redact.pdf(904.02 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

The primary data collection will be done through a web questionnaire.

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