Observational pharmaco-epidemiological study on the use of Izalgi®

First published: 18/06/2015

Last updated: 20/12/2018

Study Ongoing

Administrative details

EU PAS number

EUPAS9983

Study ID

27241

DARWIN EU® study

No

Study countries

France

Study description

Study objectives:Main objective: to describe the conditions of use of Izalgi® over a 6-month period in real treatment situations,Secondary objectives: To estimate and describe, in real 6-month treatment situations:• The

characteristics of patients treated with Izalgi®,• The misuse of the product on the following points:- Indication of Izalgi®,- Contraindications of Izalgi®,- Posology,- Duration of treatment,• A drug abuse or dependence,• The efficacy of the product,• Overall tolerance,• Adverse Drug Reactions.

Study status

Ongoing

Research institutions and networks

Institutions

CEMKA

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Pharmaco-epidemiology department, CEMKA

France

First published: 02/03/2011

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Stéphane Bouée stephane.bouee@cemka.fr

Study contact

stephane.bouee@cemka.fr

Primary lead investigator

Stéphane Bouée

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 28/03/2013

Study start date

Planned: 15/10/2015

Actual: 03/06/2016

Data analysis start date

Planned: 01/04/2017

Actual: 01/06/2018

Date of final study report

Planned: 30/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Mylan Medical SAS

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To describe the conditions of use of Izalgi® over a 6-month period in real treatment situations

Study drug and medical condition

Medicinal product name, other

IZALGI

Medical condition to be studied

Pain management

Population studied

Age groups

- Adolescents (12 to < 18 years)
- 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)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

1.300

Study design details

Outcomes

to describe the conditions of use of Izalgi® over a 6-month period in real treatment situations, To estimate and describe, in real 6-month treatment situations:• The characteristics of patients treated with Izalgi®,• The misuse of the product on the following points:- Indication of Izalgi®,- Contraindications of Izalgi®,- Posology,- Duration of treatment,• A drug abuse or dependence,• The efficacy of the product,• Overall tolerance,• Adverse Drug Reactions.

Data analysis plan

Description of the population of participating physiciansThe data collected on the physicians having participated in the study are described for the entire sample. The representativeness of the participating physicians from all GPs prescribing Izalgi® will be checked, provided that the number of response forms sent by non participants is sufficient. A comparison between the physicians and the prescribers of Izalgi® (in terms of age, sex, and region of practice) is also planned, by means of an analysis of the EGB base (cf. chapter 12.2 Representativeness of patients included).Cf protocol.

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

Longitudinal, prospective cohort follow-up study

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