A multicentre, non-interventional, prospective observational study of the use of the sufentanil sublingual tablet system (Zalviso®) for the management of acute postoperative pain in a hospital setting (ZAS)

First published: 26/01/2017

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS16829

Study ID

29857

DARWIN EU® study

No

Study countries

France

Study description

This postmarketing surveillance study pursues two aims. Firstly, the demographic and surgical characteristics of patient-controlled analgesia with Zalviso® will be studied in French patients with acute postoperative pain. Secondly, the efficacy, safety, tolerability and quality of life data will be reviewed under routine conditions of everyday clinical practice. The study will be conducted in the routine medical setting.

Study status

Finalised

Research institutions and networks

Institutions

Grünenthal GmbH

Multiple centres: 11 centres are involved in the study

Contact details

Study institution contact

Imane Wild imane.wild@grunenthal.com

Study contact

imane.wild@grunenthal.com

Primary lead investigator

Public Disclosure Grünenthal

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/09/2016

Actual: 03/04/2017

Study start date

Planned: 30/09/2016

Actual: 10/04/2017

Data analysis start date

Planned: 22/12/2017

Actual: 08/08/2018

Date of final study report

Planned: 28/09/2018

Actual: 20/12/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Grünenthal GmbH

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The demographic and surgical characteristics of patient-controlled analgesia with Zalviso® will be studied in in-patients with acute postoperative pain.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective observational study

Study drug and medical condition

Medical condition to be studied

Pain

Hospitalisation

Postoperative care

Population studied

Short description of the study population

Patients with postoperative moderate to severe acute pain who have received Zalviso®.

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)

Special population of interest

Hepatic impaired

Renal impaired

Estimated number of subjects

300

Study design details

Outcomes

The primary study endpoint is the “Patient Global Assessment of the Method of Pain Control (PGA)” questionnaire. - Course of pain on a Numeric Rating Scale (NRS) of 0-10- Quality of sleep.- Global Assessment of the method of pain control by Health Professionals (HPGA).- Safety and tolerability and "Nurse Ease of Care Questionnaires" (EoC).- Results derived from the EQ-5D will be summarized descriptively by individual parameter and summary scores.

Data analysis plan

Descriptive statistical analyses will be performed on all data collected from patients enrolled.Descriptive statistics of all endpoints will include specifically but not exclusively arithmetic mean, medians, standard deviations, minimum, maximum, proportions, frequency counts, 25th and 75th percentiles, and 95% confidence intervals of select point estimates.The primary parameters analyzed will be the pain intensity profile as well as the ease of use of the Zalviso device from the data collected in the 3 domains of the Nurse & Physical Therapist Ease of Care (EOC) Questionnaire.For the Nurse EoC questionnaire, descriptive statistics will be presented for all single items, the three subscores and the total score. Tolerability will be reported in the form of incidence of adverse drug reactions, based on MedDRA coded preferred terms.The same analysis will be done on Incident or Risk of Incident with Medical Device.

Documents

Study results

ZAS-France-Summary-of-results-Mar-2019.pdf (140.92 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

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