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 (ZEUS - Germany)

First published: 01/06/2017

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Study | Finalised

Administrative details

EU PAS number

EUPAS14689

Study ID

29351

DARWIN EU® study

No

Study countries

Germany

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 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: 10 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Public Disclosure Grünenthal

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 07/02/2017

Study start date

Actual: 16/03/2017

Data analysis start date

Planned: 15/10/2017

Date of final study report

Planned: 15/08/2018

Actual: 20/09/2018

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 & surgical characteristics of patient-controlled analgesia with Zalviso® will be studied in in-patients with acute postoperative pain. Key parameters: - Pain intensity - Max pain intensity- Quality of sleep- Postoperative mobility- Patient Global Assessment of the Method of Pain Control- Nurse & Physical Therapist Ease of Care Questionnaire for device performance.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective observational study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N01AH03) sufentanil

sufentanil

Medical condition to be studied

Pain

Hospitalisation

Postoperative care

Population studied

Short description of the study population

Patients with acute postoperative pain undergoing a broad variety of surgery types 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

Patient Global Assessment of the Method of Pain Control.Worst pain. Quality of sleep. Concomitant medication.Safety using safety reporting forms for risk assessment endpoints. Nurse & Physical Therapist Ease of Care (EOC) Questionnaire.Device performance.

Data analysis plan

Descriptive statistical analyses will be performed on all data collected from patients enrolled. An exploratory data analysis will be performed. Continous

variables will be analyzed which 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 following parameters will be analyzed: - demographic data- pain intensity profile - quality of sleep, - postoperative mobility- Patient Global Assessment of the Method of Pain Control- Nurse & Physical Therapist Ease of Care (EOC) Questionnaire for device performance).Tolerability will be reported in the form of incidence of adverse drug reactions, based on MedDRA coded preferred Terms.

Documents

Study results

ZEUS -Germany - Summary of results - Sep 2018.pdf (133.33 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