NON-INTERVENTIONAL OBSERVATIONAL STUDY FOR THE EVALUATION OF TOLERABILITY AND EFFICACY OF THE WHO-STEP III OPIOIDS OXYCODONE/NALOXONE PR AND TAPENTADOL PR UNDER DAILY LIFE CONDITIONS IN PATIENTS SUFFERING FROM NEUROPATHIC (LOW) BACK PAIN. (OXYNTA)

First published: 07/10/2015

Last updated: 02/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS11234

Study ID

11235

DARWIN EU® study

No

Study countries

Germany

Study description

Prospective, open-label, blinded endpoint (PROBE) streamlined multicentre 12-week observational study, carried out in Germany focusing on the safety, tolerability and efficacy of prolonged release (PR) preparations of oxycodone/naloxone and tapentadol in patients suffering from neuropathic (low) back pain, requiring WHO-step III opioids. Due to the open-label non-interventional study design, physicians are allowed to choose the most appropriate agent for the individual patient situation, to adjust/titrate opioid dosages as per the German prescribing information and to address all side-effects and tolerability issues as usual to achieve the best tolerability and efficacy in each individual patient.

Study status

Ongoing

Research institutions and networks

Institutions

Institute for Neurological Sciences (IFNAP)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

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Primary lead investigator

Michael Ueberall

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/01/2015

Actual: 02/01/2015

Study start date

Planned: 01/04/2015

Actual: 01/04/2015

Data analysis start date

Planned: 02/11/2015

Date of final study report

Planned: 01/04/2016

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Mundipharma, IFNAP

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

Aim of this post-hoc analysis is to evaluate the tolerability and efficacy of oxycodone/naloxone PR vs. tapentadol PR – two different newer opioid-based analgesic treatment approaches, reported to be more efficacious for neuropathic pain than the conventional opioid agonists under real-life conditions. Primary hypothesis is a non-inferiority of both treatments with respect to the primary endpoint.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

OXYCODONE

NALOXONE HYDROCHLORIDE DIHYDRATE

TAPENTADOL

Medical condition to be studied

Back pain

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Estimated number of subjects

600

Study design details

Outcomes

Primary outcome will be the percentage of patients (a) without adverse event-related study discontinuations who (b) maintained a normal bowel function (defined with the bowel function index) and (c) showed no treatment emergent adverse events affecting the central nervous system and (d) who presented with a combination of a ≥30% improvement of pain intensity, disability and quality-of-life. Percentages of patients with (a) a normal bowel function index, (b) changes in number of complete spontaneous bowel movements (CSBMs), (c) non CNS-related adverse events, (d) treatment-related changes in pain intensity, (e) disability and (f) quality-of-life.

Data analysis plan

Data analyses will be performed for all enrolled patients who took at least one dose of study medication and who had at least one post-baseline/post-dose measure (modified intent-to-treat approach). Analyses will be performed for three different patient samples to gain best insight into the real-life data and to avoid possible confounder/selection effects due to the open-label non-interventional study design: a) a random select approach – selecting patients on a pre-defined random list to eliminate possible selection effects, b) a matched paired-samples approach - selecting patients of both treatment groups according to their demographic and baseline pain characteristics to guarantee comparable baseline situations, and c) a whole data set approach – to take all observations made into consideration.

Data management

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)

Electronic healthcare records (EHR)

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

No