DIFFERENTIAL GASTROINTESTINAL EFFECTS OF WHO-STEP III OPIOIDS IN LOW BACK PAIN PATIENTS WITH VS. WITHOUT CONSTIPATION: POST-HOC ANALYSIS OF DATA FROM A 12-WEEK PROSPECTIVE, OPEN-LABEL BLINDED ENDPOINT STREAMLINED STUDY (PROBE-PHA2)

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Study Finalised

Administrative details

EU PAS number

EUPAS11048

Study ID

11049

DARWIN EU® study

No

Study countries

Germany

Study description

Post-hoc analysis of data from a prospective, randomized, open-label, blinded endpoint (PROBE) streamlined study, carried out in 88 centres in Germany, where a total of 901 patients, requiring WHO-step III opioids to treat low back pain, were enrolled, and prospectively observed for 3 months. In this post-hoc analysis, patients will be grouped with respect to their bowel function index and characterized as normal (NCP, BFI ≤28.8mm VAS, n=643) or constipated (COP, >28.8mm VAS, n=258). Treatment doses could be adjusted as per the German prescribing information and physicians were free to address all side-effects and tolerability issues as usual.

Study status

Finalised

Research institutions and networks

Institutions

Institute for Neurological Sciences (IFNAP)

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Institution

Contact details

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 08/06/2015

Actual: 08/06/2015

Study start date

Planned: 04/03/2013

Actual: 01/04/2013

Data analysis start date

Planned: 15/06/2015

Actual: 15/06/2015

Date of final study report

Planned: 31/07/2015

Actual: 31/07/2015

Sources of funding

- Other

More details on funding

Institute for Neurological Sciences

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Not applicable

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

Main objective of this post-hoc analyses is to evaluate the differential dynamics of different WHO-step III opioid-analgesics on bowel function in patients with vs. without an already established non-opioid-related constipation under real life conditions.

Study drug and medical condition

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

MORPHINE

OXYCODONE

NALOXONE HYDROCHLORIDE DIHYDRATE

Medical condition to be studied

Back pain

Population studied

Short description of the study population

Chronic low back pain (LBP) patients refractory to WHO-step I and/or II analgesics treated with WHO-step III opioids.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

- Adults (65 to < 75 years)

Special population of interest

Other

Special population of interest, other

Patients with chronic low back pain

Estimated number of subjects

901

Study design details

Outcomes

Primary criterion for this analysis is the treatment contrast for the frequency of patients with a ≥1 decline in the number of CSBMs per week. Secondary tolerability aspects are the percentages of patients (a) experiencing a clinically relevant BFI worsening (i.e. an increase ≥12 mm VAS) or (b) with a ≥50% BFI worsening vs. baseline, (c) with ≤3 CSBMs per week, and (d) with prescribed laxatives, each at the end of the 12-week observation period.

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. Linear interpolation / last observation carried forward (LOCF) method to impute missing scores. For continuous variables, descriptive statistics will be summarized by the number of patients (n), the mean, standard deviation (SD), 95% confidence intervals (95%-CI) of the mean, median, and range (minimum –maximum) values. For categorical and ordinal variables data will be summarized by frequency number (n) and percentage (%) of participants in

each category, where appropriate, 95% confidence intervals are added. For between groups comparisons of continuous/categorical variables, Student t / Pearson's chi-squared test, for within group (e.g. pre-post) comparisons paired samples t-tests will be performed.

Documents

Study publications

Ueberall MA, Mueller-Schwefe GH. Differential Gastrointestinal Effects of Who-S...

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

Aim of this post-hoc analysis is to evaluate the dynamics of bowel dysfunction as consequence of a treatment with three different WHO-step III opioids in

patients without vs. with an already established non-opioid-related constipation under real-life conditions.

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