DEVELOPMENT OF OPIOID-INDUCED CONSTIPATION: POST-HOC ANALYSIS OF DATA FROM A 12-WEEK PROSPECTIVE, OPEN-LABEL BLINDED ENDPOINT STREAMLINED STUDY IN LOW-BACK PAIN PATIENTS, TREATED WITH PROLONGED-RELEASE WHO-STEP III OPIOIDS (PROBE-PHA)

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Study Finalised

Administrative details

EU PAS number

EUPAS11039

Study ID

11040

DARWIN EU® study

No

Study countries

☐ Germany

Study description

Opioid-induced constipation (OIC) is the most prevalent patient complaint associated with longer-term opioid use and interferes with analgesic efficacy, functionality, quality-of-life, and patient compliance.Objectives of this study are to compare effects of prolonged release (PR) oxycodone and PR naloxone (OXN), vs. PR oxycodone (OXY) vs. PR morphine (MOR) on bowel function under real-life conditions in chronic low back pain (LBP) patients refractory to WHO-step I and/or II analgesics.Analyses will base on the complete data set of an already completed prospective (optionally randomized), 12-week open-label, blinded endpoint (PROBE) streamlined study (German pain study registry: 2012-0012-05, ENCEPP trial registry...), 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. Opioid allocation based on either optional randomization (453) or physician decision (448). In both groups, 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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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/03/2015

Actual: 09/03/2015

Study start date

Planned: 04/03/2013

Actual: 01/04/2013

Data analysis start date
Planned: 16/03/2015

Actual: 16/03/2015

Date of final study report
Planned: 04/05/2015

Actual: 04/05/2015

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:

Aim of this post-hoc analysis is to evaluate dynamics, extent and preventability of bowel dysfunction as consequence of a treatment with WHO-step III opioids under real-life conditions, as well as differences among the opioid analgesics used (morphine vs. oxycodone vs. oxycodone/naloxone)

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 approach is the treatment contrast for the frequency of patients maintaining a normal BFI score (≤28.8) over the whole 12-week observation period. Secondary bowel tolerability aspects are the percentages of patients (a) with a ≥50% BFI worsening at end-of-observation vs baseline, (b) experiencing a clinically relevant BFI worsening vs. baseline (i.e. an increase ≥12 mm VAS), (c) with a ≥1 decline in the number of CSBMs per week, (d) with ≥4 CSBMs per week, and (e) with prescribed laxatives, each at the end of the 12-week observation period.

Data analysis plan

Data analyses will be performed for data of all enrolled patients, who take at least one dose of study medications and have at least one post-baseline/post-dose measure. Linear/last observation carried forward (LOCF) method will be used to impute missing scores. For continuous variables, descriptive statistics will be summarized by the number of patients (n), mean, standard deviation (SD), 95% confidence intervals (95%-CI) of the mean, median, and range (min. –max.). For categorical and ordinal variables data will be summarized by frequency number (n) and percentage (%) of participants in each category. For between group 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. All statistical tests will be carried out using a 2-sided significance level of 0.05.

Documents

Study publications

Ueberall MA, Mueller-Schwefe GH. Development of opioid-induced constipation: po…

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Analyses will base on the data set of an already completed study and will constitute a subgroup-analyses focusing on distinct features of opioid-related side effects on the gastrointestinal tract

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