NON-INTERVENTIONAL RETROSPECTIVE EVALUATION OF TOLERABILITY AND EFFICACY OF TYPICAL ORAL LONG-ACTING WHO-STEP III OPIOID ANALGESICs UNDER REAL-WORLD CONDITIONS IN PATIENTS SUFFERING FROM (LOW) BACK PAIN AFTER FAILURE OF A PREVIOUS TREATMENT WITH EITHER NONOPIOID, MILD OR STRONG OPIOID ANALGESICS (123TOWHO3)

First published: 12/12/2019

Last updated: 12/12/2019

Study Finalised

Administrative details

EU PAS number

EUPAS32754

Study ID

32755

DARWIN EU® study

No

Study countries

☐ Germany

Study description

Retrospective analysis of anonymized 12-week real-world data provided by the German Pain e-Registry on the effectiveness, safety and tolerability of typical oral long-acting WHO-Step III opioid analgesics in patients with low back pain (LBP) who were previously treated with either nonopioids (group 1), mild (group 2) or strong opioid analgesics (group 3) under conditions of routine clinical practice.

Study status

Finalised

Research institutions and networks

Institutions

O.Meany-MDPM

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

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Study contact

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Primary lead investigator

Michael Ueberall

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/11/2018

Actual: 30/11/2018

Study start date

Planned: 01/01/2019

Actual: 01/01/2019

Data analysis start date

Planned: 01/04/2019

Actual: 01/09/2019

Date of final study report

Planned: 30/06/2019

Actual: 12/12/2019

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Grünenthal, German Pain Association, Institute of Neurological Sciences

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:

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To assess differential treatment effects reported by patients who were switched to the target treatment after failure of a treatment with either a) nonopioids, b) mild opioids, or c) strong opioid analgesics.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Non-randomised clinical trial

Population studied

Short description of the study population

Patients with low back pain (LBP) who were previously treated with either nonopioids (group 1), mild (group 2) or strong opioid analgesics (group 3) under

conditions of routine clinical practice.

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

Other

Special population of interest, other

Low back pain patients

Estimated number of subjects

756

Study design details

Outcomes

Percentage of patients in all 3 treatment groups who fulfilled the criteria of an aggregated5-factor symptom score (ASR-5), defined as a composite of four efficacy parameters (>=50% improvement of pain, pain-related disabilities, clinical phenomenology, and quality-of-life) and one tolerability parameter (>=12mm VAS worsening of the bowel function index). Percentage of patients in all 3 treatment groups who fulfilled at least three out of the fivecriteria of the ASR-5. Further analyses focus on treatment-related changes of pain intensityand associated parameters relevant for daily life functioning, quality-of-

life, clinical painphenomenology, concurrent analgesic treatments, bowel function and adverse events.

Data analysis plan

Exploratory analysis of anonymized 12-week routine/open-label data provided by theGerman Pain e-Registry (GPR) on adult LBP patients, in whom a treatment with strong, oral, long-acting WHO-3 opioid has been initiated in compliance with the current German prescribing regulations before December 31, 2018. LBP-patients who were switched to these treatments after failure of nonopioids were defined as group 1, those switches from mild opioids were defined as group 2 and those rotated from other strong opiods were defined as group 3. a propensity score analysis will be performed to select patients in groups 1-3 comparable to those in a previous trial performed with the atypical opioid tapentadol (WHO123TOTAP).No formal sample size analysis will be performed. Data analyses will be performed for allpatients identified through the aforementioned selection proces

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)

Disease registry

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