NON-INTERVENTIONAL RETROSPECTIVE EVALUATION OF TOLERABILITY AND EFFICACY OF THE ATYPICAL WHO-STEP III OPIOIDANALGESIC TAPENTADOL PR UNDER REAL-WORLD CONDITIONS IN PATIENTS SUFFERING FROM (LOW) BACK PAIN AFTER FAILURE OF EITHER NONOPIOID, MILD OR STRONG OPIOID ANALGESICS (123TOTAP)

First published: 09/09/2019

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS31322

Study ID

31323

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 Tapentadol – an atypical WHO-III opioid analgesic – 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: 30/06/2017

Actual: 30/11/2017

Study start date

Planned: 01/08/2017

Actual: 01/12/2017

Date of final study report

Planned: 29/06/2018

Actual: 18/06/2019

Sources of funding

- Other

- Pharmaceutical company and other private sector

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Tolerability

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)

Estimated number of subjects

756

Study design details

Outcomes

Percentage of patients in all 3 treatment groups who fulfilled the criteria of an aggregated 5-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). Percentage of patients in all 3 treatment groups who fulfilled at least three out of the five criteria of the ASR-5. Further analyses focus on treatment-related changes of pain intensity and associated parameters relevant for daily life functioning, quality-of-life, clinical pain phenomenology, concurrent analgesic treatments, bowel function and adverse events.

Data analysis plan

Exploratory analysis of anonymized 12-week routine/open-label data provided by the German Pain e-Registry (GPR) on adult LBP patients, in whom a treatment with Tapentadol has been initiated in compliance with the current German prescribing regulations before November 30, 2017. LBP-patients who

were switched to Tapentadol after failure of nonopioids were defined as group 1 and distinct baseline characteristics of this group (i.e. age, gender, severity of disease and stage of chronification) were taken as matching parameters for a propensity score analysis to find comparable pairs of patients who were switched to Tapentadol either after failure of mild (group 2) or strong opioid analgesics (group 3).No formal sample size analysis will be performed. Data analyses will be performed for all patients identified through the aforementioned selection process.

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