A real world evidence study from Germany on the safety and efficacy of tapentadol and typical oral long-acting opioid analgesics in chronic low back pain patients (1o2toTAPoLAO)

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/38333

EU PAS number

EUPAS38332

Study ID

38333

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 (GPeR) on the effectiveness, safety and tolerability of tapentadol (TAP), an atypical WHO-III opioid) and typical oral long-acting opioid analgesics (LAO) in patients with chronic low back pain (LBP) under conditions of routine clinical practice.

Study status

Finalised

Research institutions and networks

Institutions

O.Meany-MDPM

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Institution

Contact details

Study institution contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 13/08/2020

Actual: 03/09/2020

Study start date

Planned: 14/08/2020

Actual: 04/09/2020

Data analysis start date

Planned: 24/08/2020

Actual: 14/09/2020

Date of final study report

Planned: 03/12/2020

Actual: 29/11/2020

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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To assess differential treatment effects reported by chronic plow back pain patients who were switched to the index drugsafter failure of a treatment with either nonopioids or mild opioid analgesics

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Pain

Additional medical condition(s)

Chronic low back pain

Population studied

Short description of the study population

Patients with chronic low back pain.

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

Chronic low back pain patients

Estimated number of subjects

4500

Study design details

Outcomes

Responder analysis, i.e. percentage of patients who reported for pain intensity, daily life activities and physical/mental QoL absolute improvements ≥MCID and BFI changes ≤MCID (all after 12 weeks of treatment) and who didn´t stopped index treatment due to adverse drug-related events, Pain related sleep impairment assessed using the mPDI subscale and meeting the MCID, pain related sick leave as an absolute value using von Korff questionnaire, reason for discontinuation of index medication (TAP or LAO)

Data analysis plan

Exploratory analysis of anonymized 12-week routine/open-label real-world data provided by the German Pain e-Registry (GPeR) on adult patients with chronic

low back pain, in whom a treatment with Tapentadol or typical oral long-acting opioid analgesics has been initiated in compliance with the current German prescribing regulations before December 31, 2019. cLBP-patients have to be switched to index medication after failure of either nonopioid (WHO step 1) or mild opioid (WHO step 2) analgesics. Selection of treatment cases will base on a propensity score analysis (nearest neighbour technique, caliper 0.15, etc.) based on age, gender, baseline BFI, baseline pain (VAS), duration of current pain symptoms, comorbidities, previous and current pain medication group. No formal sample size analysis will be performed. Data analyses will be performed for all patients identified through the aforementioned selection process.

Data management

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