Effectiveness and tolerability of high-dose methocarbamol vs. typical strong and long-acting opioidanalgesics (LAO) as add-on measure in patients with (low) back pain refractory to recommended 1st. line treatments: retrospective analysis of open-label real-world data provided by the German Pain e-Registry. (COMET)

First published: 08/12/2020

Last updated: 23/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS38484

Study ID

38485

DARWIN EU® study

No

Study countries

☐ Germany

Study description

COMET is an exploratory non-interventional post-marketing, open-label, retrospective parallel-group, flexible-dose, comparative 4-week cohort study using depersonalized data of the German Pain e-Registry (GPeR) to assess the non-inferiority of an oral treatment with high-dose methocarbamol (Ortoton® forte, ORF) - a peripherally acting muscle relaxant - compared to typical oral long-acting opioid-analgesics (LAO) in adult patients with (low) back pain who are deemed to be in need of an alternative analgesic medication according to the mutual / shared decision of the responsible physician and the cLBP-patient after an insufficient pain relief in response to guideline-recommended systemic 1st-line treatments.

Study status

Ongoing

Research institutions and networks

Institutions

O.Meany-MDPM

First published: 01/02/2024

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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: 01/07/2020

Actual: 03/08/2020

Study start date

Planned: 14/08/2020

Actual: 21/08/2020

Data analysis start date

Planned: 15/08/2020

Actual: 01/09/2020

Date of final study report

Planned: 31/12/2020

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Recordati Pharma, 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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

Primary objective is the evaluation of the analgesic efficacy of an oral treatment with either high-dose methocarbamol (Ortoton® forte, ORF) vs. typical strong and long-acting opioid-analgesics (LAO) in comparable patient populations of the German Pain e-Registry (GPeR) with insufficient pain relief following recommended/established 1st line treatments.

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

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

750

Study design details

Outcomes

The primary efficacy variable is the absolute change of the average 24-hr. pain intensity index (PIX, calculated as the arithmetic mean of the lowest, medium and highest 24-hr. pain intensity scores reported by patients. Secondary outcomes will be based on pre-post evaluations (i.e. baseline to end of week-4 differences) for absolute/relative (percent) change of the average 24h pain intensity index (PIX), (L)BP-related disabilities in daily life (mPDI), physical/mental QoL (VR12), and EQ5D

Data analysis plan

A mixed-model repeated measures (MMRM) covariance analysis adjusted for potential confounding factors such as age, gender, pain severity (von Korff scale), stage of chronification, history/duration of pain, comorbidity, comedication, prior medication, and baseline value) will be the primary analytical technique to evaluate the primary efficacy measure. The absolute least squares (LS) mean PIX difference between treatments (cohort A minus cohort B) after 1, 2, 3, and 4 weeks of treatment along with their 2-sided 95% confidence intervals (CI) will be calculated based on the model. If the upper bound of the 95% CI does not exceed +10.0, it will be concluded that ORF is not inferior to LAO.

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