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





### Administrative details

**EU PAS number** 

**EUPAS38484** 

**Study ID** 

38485

**DARWIN EU® study** 

#### **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

Last updated: 01/02/2024

Institution

### Contact details

#### **Study institution contact**

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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: 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)

#### **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