Efficacy and tolerability of the non-benzodiazepine antispasmodic methocarbamol for the short-term treatment of acute low back pain over 3 days - results of a patient-level pooled re-analysis of depersonalized data from two double-blind randomized placebo-controlled clinical trials evaluating oral and intravenous use. (METABO)

First published: 07/12/2022

Last updated: 23/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS50070

Study ID

50071

DARWIN EU® study

No

Study countries

Germany

Study description

Patient-level pooled re-analysis of 72-hr. data from two double-blind, randomized, placebo-controlled trials evaluation the efficacy of the non-benzodiazepine antispasmodic methocarbamol (either given intravenously or orally) vs. matching placebo in adult patients with acute low back pain.

Study status

Ongoing

Research institutions and networks

Institutions

O.Meany-MDPM

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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: 01/08/2022

Actual: 30/08/2022

Study start date

Planned: 10/10/2022

Actual: 25/11/2022

Data analysis start date

Planned: 24/10/2022

Actual: 01/12/2022

Date of final study report

Planned: 09/12/2022

Sources of funding

- Pharmaceutical company and other private sector

- Other

More details on funding

Recordati, 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)

Main study objective:

The main objective of this re-analysis is to gain further insight into the differential effects of methocarbamol (given either iv or po) vs. placebo for the

immediate short-term treatment of acute low back pain in adult patients.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Patient-level pooled re-analysis of data from studies done in the past

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(M03BA03) methocarbamol

methocarbamol

Medical condition to be studied

Back pain

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

Estimated number of subjects

359

Study design details

Outcomes

The primary outcome of this study is the evaluation of the 72-hour response rate, based a) on the documented degree of pain relief (improvement ≥20mm VAS and/or ≥50% vs. baseline), b) finger-to-floor distance (improvement ≥15cm and/or ≥50% vs. baseline), c) pain-related movement restrictions (none or mild), d) Lasègue sign (negative), and e) pain-related disturbances of night sleep (none). Secondary outcomes of this study focus on the overall response to study medication for all five efficacy criteria mentioned above and all three post-baseline evaluation timepoints (24, 48, and 72 hours), percentage and timepoint of patients stopping study medication due to complete vanishing of pain, as well as premature treatment discontinuations due to adverse events, inadequate efficacy and/o

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Data analysis plan

Descriptive and inferential statistical analyses will be performed as reported. For continuous variables, descriptive statistics will be summarized by the number of patients (n), the mean, standard deviation (SD), 95% confidence intervals (95%-CI) of the mean, median, and range (minimum – maximum) values. For categorical and ordinal variables data will be summarized by frequency number (n), and percentage (%) of participants in each category, incl. 95% confidence intervals. For between groups comparisons of 2x2 contingency tables with a dichotomous/binomial trait the Chi-Square test will be applied, and Pearson's chi-squared tests will be used for categorial variables with multinomial expressions. Between groups comparisons of continuous variables will be applied dependent on the data distribution: for normally distributed data paired samples t-tests and for non-normal distributions Wilcoxon´s signed rank test will be performed.

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)

Other

Data sources (types), other

Patient-level pooled re-analysis of already existing depersonalized raw data from two clinical trials performed in 2002/2003.

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