Retrosepctive Analysis of the efficacy and tolerability of pridinol in patients with muscle pain - an analysis of open-label real-world data provided by the German Pain e-Registry (PriMePain)

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/45870

EU PAS number

EUPAS45869

Study ID

45870

DARWIN EU® study

No

Study countries

Germany

Study description

Cross-sectional retrospective analysis of anonymized real-world data provided by the German Pain e-Registry on the effectiveness, safety and tolerability of oral pridinol given as add-on treatment in patients with muscle pain (MP) in 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

Michael Ueberall

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/11/2020

Actual: 19/01/2021

Study start date

Planned: 01/01/2021

Actual: 25/01/2021

Data analysis start date

Planned: 14/01/2021

Actual: 01/02/2021

Date of final study report

Planned: 31/03/2021

Actual: 29/04/2021

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Strathmann GmbH & Co KG, O.Meany-MDPM GmbH

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:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

Main objective of this analysis is to gain further insight into the differential effects and the benefit-risk profile (BRP) of pridinol given add-on to patients with elsewhere refractory muscle pain under real life conditions.

Study Design

Non-interventional study design

Cohort

Cross-sectional

Other

Non-interventional study design, other

Cross-sectional retrospective analysis

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

PRIDINOL MESILATE

Medical condition to be studied

Musculoskeletal pain

Population studied

Short description of the study population

Patients with muscle pain (MP) in routine clinical practice who were registered in the German Pain e-Registry.

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

1100

Study design details

Outcomes

Primary efficacy endpoint analysis based on a combined responder concept. Responders are defined with respect to their response to two different criteria (at least 50% improvement and or improvement equal to or greater than th minimal clinical important difference of average 24-hour pain (PIX), pain-related disabilities in daily life (mPDI), vs. baseline. Secondary endpoints evaluate further efficacy, tolerability and safety data as provided by patients during the use of the medication under evaluation.

Data analysis plan

Exploratory analysis of anonymized routine/open-label data of the German Pain e-Registry (GPR) on adult MP patients, in whom a treatment with pridinol has been initiated in compliance with the current German prescribing regulations between January 1st 2018 and December 31st, 2020. No formal sample size

analysis will be performed. Data analyses will be performed for all registered patients who took at least one dose of study medication and who had at least one post-baseline/post-dose measure (modified intent-to-treat approach).

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

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