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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# Administrative details

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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Study 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

## **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)**

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