Pridinol vs. nsaids - efficacy/tolerability in acute (low) back pain. A propensity-score matched, comparative 2-cohort, 4-week real world evidence analysis of depersonalized data from the German Pain e-Registry in patients refractory to self-medication. (Providence)

First published: 10/11/2022

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS49718

Study ID

49719

DARWIN EU® study

No

Study countries

Germany

Study description

Retrospective analysis of anonymized 4-week real-world data provided by the German Pain e-Registry (GPeR) on the effectiveness, safety and tolerability of pridinol (PRI), a muscarinic acetylcholine receptor antagonist with antispasmodic effects and traditional nonsteroidal antiinflammatory agents (NSAIDs) in patients with acute (low) back pain (LBP) refractory to self-medication.

Study status

Finalised

Research institutions and networks

Institutions

O.Meany-MDPM

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

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Primary lead investigator

Michael Ueberall

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/07/2022

Actual: 06/07/2022

Study start date

Planned: 01/07/2022

Actual: 18/07/2022

Data analysis start date

Planned: 18/07/2022

Actual: 25/07/2022

Date of final study report

Planned: 31/10/2022

Actual: 09/11/2022

Sources of funding

- Pharmaceutical company and other private sector

- Other

More details on funding

Strathmann, German Pain Association, 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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To assess differential treatment effects reported by acute low back pain patients who were switched to the index medications after failure of pain reliefing self medication

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Back pain

Population studied

Short description of the study population

The study population included patients with acute (low) back pain received treatment with pridinol and traditional nonsteroidal anti-inflammatory agents identified through the German Pain e-Registry (GPeR).

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)

Special population of interest

Other

Special population of interest, other

Patients with low back pain

Estimated number of subjects

934

Study design details

Outcomes

Responder analysis, i.e. percentage of patients who did not discontinue treatment due to a drug-related adverse event and who reported after 4 weeks a pain intensity improvement and a reduction of pain-related disabilities ≤-20mm VAS (MCID) or ≤-50 percent vs baseline without a relevant worsening of their physical and mental quality of life. Secondary efficacy analyses will be done with respect to the absolute/relative change of pain intensity, pain-related disability in daily life, physical and mental quality of life, as well as frequency and spectrum of drug-related adverse events.

Data analysis plan

Exploratory analysis of anonymized 4-week routine/open-label real-world data provided by the German Pain e-Registry (GPeR) on adult patients with acute low

back pain, in whom a treatment with pridinol or nsaids has been initiated in compliance with the current German prescribing regulations before April 30, 2022. Selection of treatment cases will base on a propensity score analysis (nearest neighbour technique, caliper 0.15, etc.) based on age, gender as well as pain intensity (VAS), pain-related disabilities, duration of current pain symptoms, pain severity grading due to von Korff, stage of chronification, comedication, treatment indication and previous self medication. No formal sample size analysis will be performed. Data analyses will be performed for all patients identified through the aforementioned selection process.

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