Efficacy and tolerability of a 5% lidocaine medicated plaster in adult patients with localized neuropathic pain: a retrospective analysis of open-label real-world data provided by the German Pain e-Registry (EVERS)

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Study Ongoing

Administrative details

EU PAS number

EUPAS32826

Study ID

32827

DARWIN EU® study

No

Study countries

Germany

Study description

Retrospective analysis of anonymized real-world data provided by the German Paine-Registry on the effectiveness, safety and tolerability of a topical treatment with 5% lidocaine medicated plaster vs. recommended oral/systemic drugs in patients with peripheral localized neuropathic pain who showed an inadequate response to at least one recommended systemic/oral first line drug under conditions of routine clinical practice.

Study status

Ongoing

Research institutions and networks

Institutions

O.Meany-MDPM

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Institution

Contact details

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Primary lead investigator

Michael Ueberall

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 21/11/2019

Actual: 25/11/2019

Study start date

Planned: 17/12/2019

Actual: 17/12/2019

Data analysis start date

Planned: 01/01/2020

Date of final study report

Planned: 31/01/2020

Sources of funding

- Pharmaceutical company and other private sector
- Non-for-profit organisation (e.g. charity)

More details on funding

Grünenthal, 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:

Evaluation of efficacy/tolerability in comparable patient populations of the German Pain e-Registry (GPeR) with insufficient pain relief following at least one first line oral therapy for P-LNP other than post herpetic neuralgia (PHN) (single

drug or with addition of another drug) who either switched to topical 5% topical lidocaine medicated plaster or to other recommended oral 1st line drugs.

Study Design

Non-interventional study design

Cohort

Population studied

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

6000

Study design details

Outcomes

Primary endpoint: Absolute change of the average 24h pain intensity (so called pain index, PIX, mm VAS) to baseline after a treatment duration of 4 weeks, 3 months, and 6 months vs baseline, measured using a 100 mm visual analogue scale (VAS), Differential efficacy in different subgroups of P-LNP (postherpetic

neuralgia, diabetic polyneuropathiy, postsurgial neuropathic pain, and others), drug-related adverse events (systemic and local) and associated treatment discontinuations.

Data analysis plan

The absolute change of the average 24h pain intensity (so called pain index, PIX, mm VAS) to baseline after a treatment duration of 4 weeks, 3 months, and 6 months vs baseline, measured using a 100 mm visual analogue scale (VAS). A mixed-model repeated measures (MMRM) analysis adjusted for potential confounding factors such as age, gender, average 24-hour baseline pain intensity, pain severity (von Korff scale), stage of chronification, history/duration of pain (<3/≥3 months), comorbidity, subtype of P-LNP indication and prior medication) will be the primary analytical technique to assess mean change in the primary efficacy measures. The secondary efficacy objectives will be addressed by conducting MMRM and/or ANCOVA analyses. Safety will be assessed by summarizing and analyzing the frequency and spectrum of drug-related adverse events (DRAEs), and treatment discontinuations (rates and reasons).

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