Pregabalin Formulation Effectiveness in Real-World Early Response Extended-release versus immediate-release pregabalin in new patients in routine care for neuropathic pain (PREFER)

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Study Finalised

Administrative details

EU PAS number

EUPAS1000001093

Study ID

1000001093

DARWIN EU® study

No

Study countries

Germany

Study description

PREFER (Pregabalin Effectiveness and Realized Treatment Benefit in Routine Care) is a non-interventional comparative effectiveness study designed as a target trial emulation using prospectively documented routine clinical practice data from the German Pain e-Registry. The study evaluates adult patients with neuropathic or neuropathic-dominated pain initiating treatment with extended-release (ER) or immediate-release (IR) pregabalin. Eligible patients are followed for up to 12 weeks after treatment initiation. To improve comparability between treatment groups and reduce confounding by indication, patients receiving ER and IR pregabalin are balanced using propensity score matching based on predefined baseline characteristics. The study evaluates effectiveness, tolerability, dose development and optimisation, treatment persistence, and patient-reported outcomes covering pain, pain-related functioning, health-related quality of life, psychological burden and neuropathic pain characteristics. In addition to conventional comparative effectiveness analyses, prospectively specified secondary analyses evaluate Realized Treatment Benefit (RTB), a longitudinal approach that relates observed improvement to the benefit individually achievable from baseline and integrates the magnitude, timing and sustainability of treatment benefit over the observation period. PREFER aims to characterize differences between ER and IR pregabalin under routine clinical conditions and to investigate how treatment benefit develops and is realized over time.

Study status

Finalised

Research institutions and networks

Institutions

O.Meany-MDPM

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Institution

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Study timelines

Date when funding contract was signed

Planned: 01/05/2026

Actual: 06/05/2026

Study start date

Planned: 04/05/2026

Actual: 11/05/2026

Data analysis start date

Planned: 04/05/2026

Actual: 11/05/2026

Date of final study report

Planned: 08/06/2026

Actual: 12/06/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Study has been supported through an unrestricted scientific grant of ARISTO Pharma GmbH Germany

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

Study topic, other:

Neuropathic pain

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Non-interventional target trial emulation using prospectively documented German Pain e-Registry data. Patients initiating ER or IR pregabalin were followed for 12 weeks and balanced by propensity score matching to compare effectiveness, tolerability and treatment-related outcomes.

Main study objective:

To compare the effectiveness, tolerability and treatment persistence of extended-release versus immediate-release pregabalin in adults with neuropathic or neuropathic-dominated pain and to characterize treatment benefit under routine clinical care conditions.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

PREGABALIN

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

PREGABALIN

Medical condition to be studied

Pain

Additional medical condition(s)

Peripheral neuropathic pain

Population studied

Short description of the study population

The study population comprises adult patients with neuropathic or neuropathic-dominated pain receiving routine outpatient pain care in Germany who newly initiated treatment with either extended-release (ER) or immediate-release (IR) pregabalin. Eligible patients had prospectively documented baseline information prior to or at treatment initiation and at least one follow-up assessment during the predefined 12-week observation period. Patients with concomitant use of both pregabalin formulations at treatment initiation or with insufficient information to reliably determine treatment exposure were excluded.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

1.776

Study design details

Setting

Routine outpatient pain care across participating centres in Germany, based on prospectively documented real-world data from the German Pain e-Registry.

Comparators

Patients initiating extended-release (ER) pregabalin compared with patients initiating immediate-release (IR) pregabalin under routine clinical care conditions.

Outcomes

Effectiveness outcomes included pain intensity, pain-related impairment of daily activities and functioning, health-related quality of life, psychological burden, and neuropathic pain characteristics. Treatment-related outcomes included dose development and optimisation, treatment persistence, and

treatment-limiting adverse drug reactions. Prospectively specified secondary analyses assessed Realized Treatment Benefit (RTB) across 12 patient-reported outcomes over the 12-week observation period.

Data analysis plan

Descriptive analyses were performed for baseline characteristics and study outcomes. To reduce confounding and improve comparability between treatment groups, propensity scores were estimated from predefined baseline characteristics and patients initiating ER or IR pregabalin were matched 1:1 using nearest-neighbour propensity score matching. Balance was assessed before and after matching. Comparative analyses evaluated between-group differences in effectiveness, tolerability, dose development and treatment persistence over the predefined 12-week observation period. Longitudinal patient-reported outcomes were analysed at predefined assessment times. Prospectively specified secondary analyses evaluated Realized Treatment Benefit (RTB) by normalizing individual longitudinal treatment trajectories to the improvement achievable from baseline and integrating the normalized trajectories over time. Complementary analyses included the predefined ≥30% RTB responder threshold and standardized between-group effect sizes. All analyses were conducted according to the prospectively specified statistical analysis plan.

Summary results

Following propensity score matching, 888 matched datasets were analysed in each treatment cohort. Compared with IR pregabalin, patients receiving ER pregabalin achieved higher maintenance doses and a greater realized cumulative pregabalin dose over the 12-week observation period. For the predefined primary endpoint, pain-related impairment of daily activities decreased by 2.1±1.7 days/week with ER compared with 1.4±1.6 days/week with IR pregabalin (between-group difference 0.7 days/week; $p<0.001$; SMD

0.43, 95% CI 0.33–0.52), while improvements across all major patient-reported outcome measures consistently favoured ER pregabalin. Treatment-emergent ADRs occurred less frequently (24.4% vs. 40.5%), ADR-related treatment discontinuations were reduced, and treatment persistence at Week 12 was substantially higher with ER vs. IR pregabalin (80.9% vs. 58.3%; all p<0.001).

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 source(s), other

German Pain e-Registry

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

No

Data characterisation moment

after data extraction