Capsaicin 179 mg cutaneous patch treatment in adult patients with peripheral localized neuropathic pain – A retrospective study to document initial/progressive response and develop a responder profiling algorithm based on the number of treatments in a longitudinal analysis of depersonalized bio-psycho-social real-world data of a subset of the German Pain e-Registry (CASPAR)

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000106

EU PAS number

EUPAS1000000106

Study ID

1000000106

DARWIN EU® study

No

Study countries

☐ Germany

Study description

CASPAR is an exploratory, non-interventional, post-marketing, open-label, retrospective, flexible-dose, longitudinal (at least 1-year) single-cohort-study using depersonalized data of a subset of the German Pain e-Registry (GPeR; until December 31st, 2022) on patients who were treated as part of a special/integrated care contract of the Integrative Managed Care (IMC) Corporation - so-called IV Pain concept - for at least 12 months to assess the effectiveness and global response of capsaicin 179 mg patches in adult patients who are deemed to be in need of such a treatment according to the mutual / shared decision of the responsible physicians and affected patients. Based on the evaluated early (to 1st) and delayed (to 3rd patch) response to treatment, demographic and bio-psycho-social data are planned to be traced backward to baseline to identify critical parameters and their predictive value for a beneficial response to a treatment with capsaicin 179 mg to identify clinically useful predictors for response.

This study exclusively evaluates the effectiveness of the topical application of capsaicin 179 mg cutaneous patches in patients with locally circumscribed peripheral neuropathic pain. Analyses base on anonymized real-world data of a subset of the GPeR – a national web-based pain treatment registry developed by the Institute of Neurological Sciences and hosted by the O.Meany-MDPM corporaration – that have originally been prospectively sampled for routine care

purposes as part of a special/integrated care contract termed IV-Pain developed by the Integrative Managed Care (IMC) corporation. Data are entered by using electronic case report forms as provided by the GPeR and the related online documentation service iDocLive®.
Analyses are planned for definite patient cohorts characterized by identical/comparable pain mechanisms/causes - such as pstherpetic neuralgia (PHN), peripheral nerve injury (PNI), peripheral diabetic polyneuropathy (PDPN), and others (OTH).

Study status

Finalised

Research institutions and networks

Institutions

O.Meany-MDPM

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Institution

Institute for Neurological Sciences (IFNAP)

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Institution

Contact details

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Study timelines

Date when funding contract was signed

Planned: 04/09/2023

Actual: 04/09/2023

Study start date

Planned: 01/10/2023

Actual: 01/10/2023

Data analysis start date

Planned: 15/10/2023

Actual: 15/10/2023

Date of final study report

Planned: 01/05/2024

Actual: 01/04/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

The retrospective GPeR (IV-S) study CASPAR is sponsored in part by Grünenthal (80%) and IFNAP (20%).

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 type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Evaluation of patient-reported outcomes

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

CASPAR is an exploratory, non-interventional, post-marketing, open-label, retrospective, flexible-dose, longitudinal, multi-cohort-study using depersonalized data of the German Pain e-Registry (GPeR) to assess the progressive response of HCCP in patients with peripheral/localized neuropathic pain.

Main study objective:

The primary objective of this study is the evaluation of (progressive) response to capsaicin 179 mg treatment [i.e. the percentage of patients who reported a reduction of the highest 24-hr. pain intensity (HPI) either ≥30% or ≥20mm VAS (the minimal clinical important difference, MCID) vs baseline, plus a significant improvement of neuropathic pain-related disabilities in daily life (either ≥30% or ≥20mm VAS vs. baseline), plus a significant change in neuropathic pain phenomenology (either ≥30% or ≥2 points of the PDQ7 score)] in an adult patient population of the German Pain e-Registry (GPeR), who suffer from peripheral/localized neuropathic pain based on the number of applications.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

QUTENZA 179 MG - CUTANEOUS PATCH

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

CAPSAICIN

Anatomical Therapeutic Chemical (ATC) code

(N01BX04) capsaicin

capsaicin

Additional medical condition(s)

Peripheral (localized) neuropathic pain

Population studied

Short description of the study population

CASPAR is an exploratory, non-interventional, post-marketing, open-label, retrospective, flexible-dose, longitudinal (at least 1-year) single-cohort-study using depersonalized data of specific subset of the German Pain e-Registry (GPeR; until December 31st, 2022) to assess the effectiveness and global response of high concentration (179 mg) capsaicin patches (HCCP) in adult patients with peripheral (localized) neuropathic pain.

Depersonalized date of the GPeR - which has originally been generated as part of specific/integrated care contract developed and hosted on behalf of a group national German statutory health insurance funds are selected for this analysis if the following inclusion criteria are fulcfilled:

Adult patients (≥18 years of age) suffering from localized peripheral neuropathic pain.

Patients in whom a treatment with index medication (capsaicin 179 mg

cutaneous patch) has been initiated for the first time (index date) for the treatment of their localized/peripheral neuropathic pain, by the current treating physicians based on individual patient needs, including but not restricted to a persistence/increase/worsening of neuropathic pain, a decrease/worsening/ deterioration in functional status/activity, decreasing response to prior medication, intolerance/contraindications to or ineffectiveness of prior treatments, etc.
Patients must have a complete documentation with respect to all parameters necessary for evaluation at baseline and must be part of the GPeR-network for the full follow up period of at least 1-year after the first treatment with the index medication irrespective of the number of times the index medication has been used (as confirmed by an electronically documented online activity beyond the evaluation period).
Data will be excluded if patients suffer from a progressive disorder, or critical pain-independent psychological comorbidities incl. drug or alcohol abuse, or show any signals for a critical drug dependency, or if they provide incongruent or missing data with respect to the parameters necessary for the evaluation of the primary/secondary endpoints.

Age groups

Adult and elderly population (≥18 years)

Estimated number of subjects

2574

Study design details

Setting

Retrospective analysis of depersonalized data of the German Pain e-Registry on patients who received between January 1st, 2105 and December 31st, 2022 at least one HCCP treatment and who documented their pain progression over at least the next 12 months.

Comparators

Only treatments with capsaicin are evaluated.

Outcomes

Efficacy analyses focus:

1) on the percentage of patients, who:
a) report an absolute/relative reduction of the average 24-hr. pain intensity (PIX) ≥30, or ≥20mm VAS vs. baseline
b) become completely pain free
c) switch from one PDQ7 category (probably no neuropathic pain, unclear, probably neuropathic pain) to another
d) start/discontinue/adjust pharmacological treatments with other analgesic/adjuvant drugs for their neuropathic pain
e) report an absolute/relative improvement of their pain-related disability in daily life (as assessed with the modified pain disability index, mPDI) ≥30% and/or ≥20mm VAS vs. baseline
f) report an absolute/relative improvement of their sleep at night quality (as assessed with the mPDI subscale #6) ≥30% or ≥20mm VAS vs. baseline
g) report adverse drug-reactions (ADRs)

2) the absolute/relative change vs baseline of the:
a) lowest, medium, and highest 24-hr pain intensity (LPI, API, HPI)

b) average 24-hr. pain intensity index (PIX)

c) pain-related disabilities in daily life (mPDI)

d) physical and mental quality of life (VR12-PCS/MCS)

e) pain phenotype (PDQ7 incl. individual PDQ7 parameters)

f) overall wellbeing (MQHHF)

3) frequency and spectrum of documented ADRs and related treatment discontinuations;

4) use of systemic/conventional analgesic and co-analgesic pharmacotherapies (type and dose);

5) number of capsaicin 179 mg cutaneous patches used per application and intervals between applications.

Data analysis plan

Data analyses will be performed for the complete set of anonymized as-observed-data data as provided by the GPeR according to the given in- and exclusion criteria and follows a modified intent-to-treat (ITT) approach as any data of patients who (a) fulfill the in- and exclusion criteria, (b) take/record at least one application of the treatment under evaluation and (c) record at least one post-baseline/post-dose measure within the defined evaluation frame (at least 1-year) will be evaluated.

When changes from baseline to endpoints are assessed, data will be included in the analysis only if there is a baseline and a corresponding postbaseline measure.

All outcomes will be summarized descriptively for baseline and absolute and relative change from baseline using appropriate summary statistics and/or frequency distributions.

Safety analyses will be conducted on the safety analysis set. This set includes

data of all patients who record at least one dose of the drugs under evaluation. Descriptive and inferential statistical analyses will be performed as reported. For continuous variables, descriptive statistics will be summarized by the number of patients (n), the mean, standard deviation (SD), 95% confidence intervals (95%-CI) of the mean, median, and range (minimum – maximum) values. For categorical and ordinal variables data will be summarized by frequency number (n), percentage (%) and (where appropriate) adjusted percentage (a%) of participants in each category, incl. 95% confidence intervals. For between subgroup comparisons of 2x2 contingency tables with a dichotomous/binomial trait the Chi2 test will be applied, and Pearson's Chi2 tests will be used for categorial variables with multinomial expressions. Between subgroup comparisons of continuous variables will be applied dependent on the data distribution: for normally distributed data paired samples t-tests and for non-normal distributions Wilcoxon´s signed rank test will be performed. etc.

Data management

Data sources

Data source(s), other

German Pain e-Registry

Data sources (types)

Disease registry

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