Exploratory non-interventional, open-label, prospective, longitudinal 12-week parallel group study to assess the efficacy and safety of a balanced (10mg:10mg) THC/CBD cannabinoid extract in adult patients* suffering from otherwise refractory chemotherapy-induced neuropathic pain (CINP). (OCEAN)

First published: 11/08/2023

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS106298

Study ID

106299

DARWIN EU® study

No

Study countries

Germany

Study description

Non-interventional 12-week observational two-cohort study to evaluate the efficacy and tolerability of an add-on tretament with a balanced 10:10 THC:CBD cannabinoid in patients with chemotherapy-induced neuropathic pain (CINP) refractory to guideline recommended treatments. Patients will receive treatment with the cannabinoid under evaluation according to national German practice guidelines and dependent of cost coverage by stautory health insurance companies: data of patients who fulfilled the in- and exclusion criteria and for whom their insurances agree to cover the costs of the cannabinoid treatment will be aggregated in cohort A and patients for whom the cost coverage will be declined will be aggregated in cohort B.

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: 31/03/2023

Actual: 17/05/2023

Study start date

Planned: 09/08/2023

Actual: 09/08/2023

Data analysis start date

Planned: 09/08/2023

Actual: 09/08/2023

Date of final study report

Planned: 09/08/2023

Actual: 09/08/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Avextra Pharma 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:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The aim of OCEAN is to gain knowledge about the specific safety, tolerability and efficacy of the cannabinoid cultivar Jack Haze and its application in the form of a full-spectrum extract balanced in terms of THC and CBD content (10:10) in adult patients with otherwise therapy-difficult chemotherapy-induced neuropathic pain (CINP) under everyday conditions (so-called real-world evidence).

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Exploratory, open-label, prospective, longitudinal 12-week parallel group study

Study drug and medical condition

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

DELTA(9)-TETRAHYDROCANNABINOLIC ACID

CANNABIDIOL

Medical condition to be studied

Neuralgia

Additional medical condition(s)

Chemotherapy-induced neuropathic pain

Population studied

Short description of the study population

Adult patients with refractory chemotherapy-induced neuropathic pain received cannabinoid extract as add-on treatment with standard of care identified from 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)

Special population of interest

Other

Special population of interest, other

Patients with refractory chemotherapy-induced neuropathic pain

Estimated number of subjects

400

Study design details

Outcomes

Primary endpoint is the proportion of patients in both cohorts who shall report at end of week 12 vs. baseline either an absolute improvement ? the minimal clinical important difference (MCID) or a relative improvement ? 30% for a) average 24-hr. pain intensity, b) pain-related disabilities in daily life, c) pain-related sleep disturbances, and d) neuropathic pain phenomenology. Efficacy: absolute and relative changes at end of week 12 vs. baseline for all single items of the primary endpoint. Safety/tolerability: number and spectrum of adverse drug reactions (ADRs), proportion of patients affected by ADRs.

Data analysis plan

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 groups comparisons of 2x2 contingency tables with a dichotomous/binomial trait McNemar´s test (with the Edwards correction) will be applied, and Pearson's chi-squared tests will be used for categorial variables with multinomial expressions. Between groups 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.

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)

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