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

PURI

https://redirect.ema.europa.eu/resource/106293

EU PAS number

EUPAS106292

Study ID

106293

DARWIN EU® study

No

Study countries

☐ Germany

Study description

Open 12-week parallel two-cohort non-interventional evaluation of the efficacy and tolerability of a balanced 10:10 THC:CBD full spectrum cannabinoid extract as add-on treatment to standard of care in adult patients with elsewhere refractory chemotherapy-induced neuropathic pain, based on real-world data provided by the German Pain e-Registry.

Study status

Finalised

Research institutions and networks

Institutions

O.Meany-MDPM

First published: 01/02/2024

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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 type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

12-week Efficacy and tolerability of a balanced 10:10 THC:CBD full spectrum extract vs. standard of care.

Study Design

Non-interventional study design

Cohort

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

~300 patients with the cannabinoid under evaluation for whom the cost coverage has been accepted by the responsible statutory insurance company; ~ 100 patients for whom cost coverage has been rejected by the responsible statutory insurance company and who received a standard of care treatment.

Observation time is 12 weeks from date of the decision regarding cost coverage.

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

400

Study design details

Outcomes

Primary endpoint of this study is the number of patients who reported either an absolute improvement equal to or greater than the minimal clinical important difference or a relative improvement equal to or greater than 30% vs. baseline for a) average 24-hour pain intensity, pain-related disabilities in daily life, pain-related sleep disturbances, and neuropathic pain phenomenology., Efficacy: absolute/relative treatment-related changes in average 24-hour pain intensity, pain-related disabilities in daily life, pain-related sleep disturbances, and neuropathic pain phenotype at end of week 12 vs. baseline. Safety/tolerability: number and spectrum of reported adverse drug reactions, percentage of patients affected by adverse drug reactions.

Data analysis plan

Descriptive and inferential statistical analyses will be performed. 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 will be used.

Data management

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