Effectiveness and tolerability of the THC:CBD oromucosal spray as add-on measure in patients with severe chronic pain: analysis of 12-week open-label real-world data provided by the German Pain e-Registry (ETORO-PAIN)

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/25800

EU PAS number

EUPAS25799

Study ID

25800

DARWIN EU® study

No

Study countries

☐ Germany

Study description

Cross-sectional retrospective analysis of anonymized real-world data provided by the German Pain e-Registry on the effectiveness, safety and tolerability of an oromucosal spray containing delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD), given as add-on treatment in patients with severe chronic pain (SCP) in routine clinical practice.

Study status

Planned

Research institutions and networks

Institutions

Institute for Neurological Sciences (IFNAP)

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Institution

Contact details

Study institution contact

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Primary lead investigator

Michael Ueberall

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/11/2017

Study start date
Planned: 10/03/2017

Data analysis start date
Planned: 29/01/2018

Date of interim report, if expected
Planned: 08/03/2018

Date of final study report
Planned: 15/06/2018

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Almirall Hermal GmbH Germany, IFNAP - 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:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

Main objective of this analysis is to gain further insight into their differential effects and the benefit-risk profile (BRP) of THC:CBD oromucosal spray given add-on to patients with elsewhere refractory severe chronic pain under real life conditions.

Study Design

Non-interventional study design

Cohort

Cross-sectional

Study drug and medical condition

Name of medicine, other

Sativex

Medical condition to be studied

Musculoskeletal pain

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

800

Study design details

Outcomes

Primary efficacy endpoint is an aggregated 9-factor symptom relief score (ASR-9) defined as a composite of nine efficacy parameters (at least 50% improvement of pain, pain-related disabilities in daily life, sleep, overall wellbeing, physical and mental quality-of-life, depression, anxiety and stress, each at end of observation vs. baseline). Safety endpoints is the spectrum of treatment emergent adverse reactions (TEAEs) and the proportion of related treatment discontinuations.

Data analysis plan

Exploratory analysis of anonymized 12-week routine/open-label data of the German Pain e-Registry (GPR) on adult SCP patients, in whom a treatment with THC:CBD has been initiated in compliance with the current German prescribing regulations between March 10th and December 31st, 2017. No formal sample size analysis will be performed. Data analyses will be performed for all registered patients who took at least one dose of study medication and who had at least one post-baseline/post-dose measure (modified intent-to-treat approach). Analyses will be performed for patient samples with nociceptive, mixed or neuropathic pain identified with the modified 7-dimensional patient-reported pain detect questionnaire (PDQ7) to gain best insight into the effectiveness of THC:CBD in different pain mechanisms.

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

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