Longitudinal analysis of the efficacy and tolerability of dronabinol use in patients with severe ± chronic pain – a retrospective analysis of open-label real-world data provided by the German Pain e-Registry. (ReDroPain)

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/35351

EU PAS number

EUPAS35350

Study ID

35351

DARWIN EU® study

No

Study countries

☐ Germany

Study description

Cross-sectional retrospective analysis of anonymized real-world data provided by theGerman Pain e-Registry on the effectiveness, safety and tolerability of oral dronabinol given as add-on treatment in patients with severe chronic pain (SCP) in routine clinical practice.

Study status

Planned

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: 13/12/2019

Study start date
Planned: 02/01/2020

Data analysis start date
Planned: 03/02/2020

Date of interim report, if expected
Planned: 28/02/2020

Date of final study report
Planned: 30/04/2020

Sources of funding

- Pharmaceutical company and other private sector

- Other

More details on funding

Canada Inc. DBA Spectrum Therapeutics, O.Meany-MDPM 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:

Main objective of this analysis is to gain further insight into the differential effects and thebenefit-risk profile (BRP) of dronabinol given add-on to patients withelsewhere refractory severe chronic pain under real life conditions.

Study Design

Non-interventional study design

Cohort

Cross-sectional

Study drug and medical condition

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

DRONABINOL

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

1145

Study design details

Outcomes

Primary efficacy endpoint analysis based on a combined responder concept. Responders are defined with respect to their response to four different criteria (at least 50% improvement of pain, pain-related disabilities in daily life, quality-of-life,depression, sleep, each at end of observation vs. baseline), Secondary endpoints evaluate further efficacy, tolerability and safety data as provided by patients during the use of the medication under evaluation.

Data analysis plan

Exploratory analysis of anonymized 12-week routine/open-label data of the German Paine-Registry (GPR) on adult SCP patients, in whom a treatment with dronabinol has beeninitiated in compliance with the current German prescribing regulations between March 10th and December 31st, 2018. 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).

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