# Effectiveness and tolerability of the THC:CBD oromucosal spray vs. typical oral long-term opioid-analgesics in patients with severe neuropathic (low) back pain: retrospective analysis of open-label real-world data provided by the German Pain e-Registry (NABILA-NBP)

**First published:** 12/01/2021

**Last updated:** 02/04/2024

Study Planned

## Administrative details

**EU PAS number**

EUPAS38969

**Study ID**

38970

**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) vs. typical oral long-term opioid-analgesics, given as add-on treatment in patients with severe chronic neuropathic (low) back pain (NBP) in routine clinical practice.

**Study status**

Planned

# Research institutions and networks

## Institutions

### Institute for Neurological Sciences (IFNAP)

**First published:** 01/02/2024

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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: 30/09/2020

**Study start date**
Planned: 01/10/2020

**Data analysis start date**
Planned: 15/10/2020

**Date of final study report**
Planned: 31/12/2020

## 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

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

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**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 the benefit-risk profile (BRP) of THC:CBD oromucosal spray vs. typical oral long-acting opioid-analgesics given add-on to patients with elsewhere refractory severe chronic neuropathic (low) back pain under real life conditions.

## Study Design

**Non-interventional study design**

Cohort

Cross-sectional

## Study drug and medical condition

**Name of medicine, other**

Sativex

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

MORPHINE

HYDROMORPHONE

OXYCODONE

**Medical condition to be studied**

Neuropathy peripheral

**Additional medical condition(s)**

Neuropathic (low) back 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**

1300

# 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). Secondary endpoint is the spectrum of treatment emergent adverse reactions (TEAEs) and the proportion of related treatment discontinuations.

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**Data analysis plan**

Exploratory analysis of anonymized 24-week routine/open-label data of the German Pain e-Registry (GPR) on adult NBP patients, in whom a treatment with THC:CBD oromucosal spray or with a typical oral long-acting-opioid analgesic (LAO) has been initiated in compliance with the current German prescribing regulations between March 10th and July 31st, 2020. No formal sample size analysis will be performed. Data analyses will be performed for all registered patients who took at least one dose of the THC/CBD oromucosal spray and comparable patients treated with LAO, who had at least one post-baseline/post-dose measure (modified intent-to-treat approach). Analyses will be performed only for patients with neuropathic (low) back pain identified with the modified 7-dimensional patient-reported pain detect questionnaire (PDQ7).

# 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 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