# Eine nicht-interventionelle, offene, prospektive Studie zur Beurteilung des Einflusses und der Sicherheit eines ausgewogenen (10mg:10mg) THC/CBD-Extrakts auf die Schlafqualität und Schmerzempfindung bei chronischen Schmerzpatient/innen. (IMprovement of sleep in PAin patients under Cannabis Treatment) (IMPACT)

**First published:** 22/11/2023

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Study Ongoing

## Administrative details

**EU PAS number**

EUPAS107696

**Study ID**

107697

**DARWIN EU® study**

No

**Study countries**

Germany

**Study description**

Sleep is a physiological process, that has an important role in physical recovery and relaxation and therefore is essential for the maintanance of vital functions. Chronical sleep disturbances, as insomnia and obstructive sleep apnea, are of health risk, as they are associated with depression, cardiovascular diseases and dementia. An association of the Endocannabinoid system with the sleep-wake cycle could be shown in studies for human and animals. Several randomized clinical studies already demonstrated first hints that medical Cannabis or Cannabinoids in comparison to placebo can improve the quality of sleep as well as sleep interruptions in patients with chronical tumour-related and non-tumour-related pain. Similar effects were reported in self-assessments of patients regarding sleep quality, sleep interruptions and falling-asleep duration. However, there are not enough evidences for the use of Cannabinoids as secure and effective routine treatment for sleep disturbances, yet. Encouraging results of newer studies justify further clinical studies to investigate the potential role of Cannabinoids in treatment of sleep disturbances. Thereby, the effect on the quality of sleep and by that on pain intensity of chronic pain patients is of special interest.

**Study status**

Ongoing

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Richard Ibrahim

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 01/06/2023

Actual: 01/06/2023

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**Study start date**

Planned: 15/06/2023

Actual: 15/06/2023

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**Data analysis start date**

Planned: 01/05/2024

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**Date of final study report**

Planned: 30/08/2024

## Sources of funding

- Other
- Pharmaceutical company and other private sector

## More details on funding

Avextra Pharma GmbH, Pain Technologies and Clinical Monitoring GmbH

## 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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**Main study objective:**

Effect of insomnia in chronic pain patients: Relative improvement on the "Regensburger Insomnie Skala" (RIS, sum of points) versus baseline of 30% at minimum. AND/OR Absolute RIS-Verbesserung (sum of points) versus baseline

by minimal 5 (minimal clinically important diffeerence, MCID).

## Study Design

**Non-interventional study design**

Cohort

## 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)

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**Estimated number of subjects**

100

## Study design details

**Outcomes**

Effect of insomnia in chronic pain patients: Relative improvement on the "Regensburger Insomnie Skala" (RIS, sum of points) versus baseline of 30% at minimum. AND/OR Absolute RIS-Verbesserung (sum of points) versus baseline by minimal 5 (minimal clinically important diffeerence, MCID). 1. Effect of THC/CBD on pain intensity (Reduction of mean pain intensity): 2. Evaluation of

safety and tolerability of THC/CBD. 3. Effect of THC/CBD on Co-medication / reduction of polypharmacy.

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**Data analysis plan**

No formal sample size calculation is performed for this exploratory study. Therefore, the interpretation of the change in sleep quality and pain perception will be modelled with a focus on effect size and confidence intervals to account for statistical error parameters. Exploratory analyses will be conducted for all patients participating in the study. Special (exploratory) subgroup analyses of interest are e.g. pain indication, gender. For univariate descriptive statistics, continuous data are summarised by sample size, mean, standard deviation, median and range, using additional descriptors where appropriate. Categorical data are counted by number and percentage of participants.

# 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)**

Other

## 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