Retrospective, non-interventional, longitudinal, multi-cohort/parallel group study to assess the safety, tolerability, and efficacy of analgesic therapy with cannabinoids vs. non-cannabinoids in CKD patients with peripheral neuropathic pain/muscle pain depending on the degree of renal impairment (ICD10: N18.1-5) using depersonalized 6-month data from the German Pain e-Registry (CANRELIEF)

First published: 17/09/2025

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Study Finalised

Administrative details

EU PAS number

EUPAS1000000738

Study ID

1000000738

DARWIN EU® study

No

Study countries

☐ Germany

Study description

CANRELIEF is a non-interventional, retrospective analysis of anonymized data from the German Pain E-Register, in which routine data from daily care are used to evaluate the efficacy and tolerability of cannabis-based pain medications compared to approved standard analgesics and co-analgesics in adults with chronic kidney dysfunction.

The main feature of the treatment documentation is the prescription of various active ingredients for pain treatment within the framework of the applicable national laws and prescription options in Germany (including the Act Amending the Narcotics Act and Other Regulations (§ 31 (6) SGB V) and the use of the online documentation software iDocLive® for standardized observation of the course of treatment in accordance with the usual standards of care over a period of at least 6 months.

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

Michael Ueberall michael.ueberall@omeany.de

Study contact

michael.ueberall@omeany.de

Primary lead investigator

Michael Ueberall

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/06/2025

Actual: 05/06/2025

Study start date

Planned: 06/06/2025

Actual: 06/06/2025

Data analysis start date

Planned: 01/07/2025

Actual: 01/07/2025

Date of interim report, if expected
Planned: 02/09/2025

Actual: 02/09/2025

Date of final study report
Planned: 30/09/2025

Actual: 09/09/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

IFNAP

private Institute of Neurological Sciences

Nordostpark 51

90411 Nürnberg

STADAPHARM GmbH

Stadastraße 2-18

61118 Bad Vilbel

Deutschland

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Retrospective, non-interventional evaluation of depersonalized routine-data provided by the German Pain e-Registry on patients with chronic kidney disease who suffer from nociceptive or neuropathic pain and who received either an

analgesic standard treatment with guideline recommended drugs or a can

Main study objective:

The primary objective of this non-interventional study is to comparatively evaluate the safety, tolerability, and efficacy of cannabis-based pain therapy (CAM) compared to conventional pain therapy with analgesics and co-analgesics recommended by guidelines (NCAM) in adult patients with varying degrees of chronic renal impairment (ICD-10: N18.1-5) under everyday conditions.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

cannabis-based medicine

standard analgesics and co-analgesics

Medical condition to be studied

Chronic kidney disease

Additional medical condition(s)

nociceptive and neuropathic pain

Population studied

Short description of the study population

Retrospective, non-interventional evaluation of depersonalized routine-data provided by the German Pain e-Registry on patients with chronic kidney disease who suffer from nociceptive or neuropathic pain and who received either an analgesic standard treatment with guideline recommended drugs or a cannabis-based alternative.

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Renal impaired

Estimated number of subjects

2054

Study design details

Setting

For this purpose, routine data from the German Pain E-Register will be mirrored, anonymized, and stratified into two treatment cohorts according to defined inclusion and exclusion criteria. To ensure comparable baseline values, a so-

called propensity score matching (PSM) is performed, in which each patient treated with CAM is matched with a patient treated with NCAM [in terms of age, gender, pain phenotype, duration of illness, degree of renal dysfunction, etc. (Note: Patients for whom no suitable “partner” from the other treatment group can be found in the PSM are excluded from the analysis without replacement; a PSM performed in mid-2025 based on the above-mentioned target criteria identified 1027 evaluable patients with at least 6 months of follow-up data for each of the two comparison groups). In addition to demographic data and baseline data, treatment-related changes in pain intensity (lowest, mean, and highest 24-hour pain intensity values, 24-hour pain index – PIX), pain-related impairments (modified Pain Disability Index, mPDI), pain-related impairments of mood and affect (DASS-21, areas of depression, anxiety, and stress), pain-related limitations of quality of life (Quality-of-Life Impairment by Pain Inventory, QLIP), as well as daily cannabis dose and the need for or use of other analgesics and co-analgesics were recorded at three assessment points: baseline (i.e., immediately before the start of cannabis therapy) and at the end of months 3 and 6 of treatment.

Comparators

Cannabis-based analgesics (CAM: either pure THC, THC-dominant, CBD-dominant, or pure CBD) will be compared to conventional Non-Cannabis pain medications.

Outcomes

Primary endpoint of CANRELIEF is the percentage of patients who did not discontinue pain medication due to adverse drugs reactions (ADR) and who reported a clinically relevant improvement vs. baseline (i.e. a symptom relief equal to or even greater than the minimal clinical important difference for the resepctive parameter and/or at least 30%) for a) average 24-hr. pain intensity

index (PIX), b) modified pain disability index (mPDI), c) pain-related sleep disturbances (mPDI subscale #6), d) quality-of-life impairment by pain (QLIP), e) overall wellbeing, f) number of days impaired by pain in the last 3 months, and g) overall impact of pain in the last 3 months.

Data analysis plan

The primary endpoint, like all other efficacy and tolerability analyses conducted as part of this study, will be evaluated for the “as observed” (AOD) data set and as part of a sequential non-inferiority/superiority analysis. All analyses are based on a comparison of the data at the end of the third/sixth month with the corresponding baseline data.

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 source(s), other

German Pain e-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