DARWIN EU® - Drug utilisation study on medicinal use of cannabis flos

First published: 25/06/2024

Last updated: 19/02/2025

Study Finalised

Administrative details

EU PAS number

EUPAS1000000228

Study ID

1000000228

DARWIN EU® study

Yes

Study countries

- [ ] Germany
- [ ] Netherlands

Study description

Cannabis flos (dried, whole or fragmented, flowering tops of Cannabis sativa L.) is not registered as medicinal product in the European Union (EU).

However, there are different regulatory strategies among EU member states that enable some specific exemptions for its use and its supply by pharmacies, as a controlled substance under physician’s prescription only.
Scientific data is needed to inform and support regulatory work including a possible establishment of an EU herbal monograph.

Research question
What is the (real-world) use of Cannabis flos that is prescribed for medicinal purposes?

Study objectives
1. To estimate incidence rates and prevalence of use of Cannabis flos, overall and stratified by pre-specified medicinal product of interest, age, sex and country/database, during the study period from 2014 to 2023.
2. To characterise the cohort of patients being treated with the Cannabis flos at the time of new prescription/dispensation of the selected medicinal products in terms of demographics, indication for prescribing/dispensing, comorbidities and comedication.
Additionally, to determine duration of treatment with Cannabis flos products and optionally, to describe the route of administration. Results will be stratified by pre-specified medicinal product of interest and database.

Study status
Finalised

Research institutions and networks

Institutions

IQVIA NL, Real-World-Evidence

☐ Netherlands

First published: 25/11/2022

Last updated: 21/03/2025

Institution | Other | ENCePP partner

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

☐ Belgium
☐ Croatia
☐ Denmark
☐ Estonia
☐ Finland
☐ France
☐ Germany
☐ Greece
☐ Hungary
☐ Italy
☐ Netherlands
☐ Norway
☐ Portugal
☐ Spain
☐ Sweden

United Kingdom

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Dina Vojinovic

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/04/2024

Actual: 16/04/2024

Study start date

Planned: 08/07/2024

Date of final study report

Planned: 30/08/2024

Actual: 22/10/2024

Sources of funding

- EMA

Study protocol

DARWIN EU_D2.2.3_Protocol_P3-C1-006_DUS_Cannabis flos_V3.0.pdf(905.5 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Herbal medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

A cohort study will be conducted using routinely collected health data from 2 databases.

Main study objective:

1. To estimate incidence rates and prevalence of use of Cannabis flos, overall and stratified by pre-specified medicinal product of interest, age, sex and country/database, during the study period from 2014 to 2023.
2. To characterise the cohort of patients being treated with the Cannabis flos at the time of new prescription/dispensation of the selected medicinal products in terms of demographics, indication for prescribing/dispensing, comorbidities and comedication.

Additionally, to determine duration of treatment with Cannabis flos products and optionally, to describe the route of administration.

Results will be stratified by pre-specified medicinal product of interest and database.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Cannabis flos (dried, whole or fragmented, flowering tops of Cannabis sativa L.) - Bedrocan, Bedrobinol, Bediol, Bedrolite, Bedica and any other Cannabis flos containing products, provided such products are available in the datasets of interest.

Medical condition to be studied

Cancer pain

Anxiety disorder

Muscle spasticity

Multiple sclerosis

Spinal cord injury

Epilepsy

Tourette's disorder

Huntington's disease

Parkinson's disease

Amyotrophic lateral sclerosis

Glaucoma

HIV infection

Anorexia nervosa

Insomnia

Inflammatory bowel disease

Fibromyalgia

Rheumatoid arthritis

Additional medical condition(s)

Neuralgic pain, cancer, anxiety-related disorders, neurological disorders (epilepsy, Tourette Syndrome, Huntington, Parkinson disease, amyotrophic later sclerosis (ALS), Alzheimer and other dementias), sleep disorders (insomnia, sleep apnea), rheumatoid arthritis.

Population studied

Short description of the study population

Population-level utilisation of selected medicinal products of interest:
Population-level drug utilisation analyses will include all individuals registered in the respective databases between 1st of January 2014 and 31st of December 2023, with at least 1 year of data visibility prior becoming eligible for study inclusion.
This requirement of at least 1 year of prior data history will not hold for children <1 year of age.

Patient-level utilisation of selected medicinal products of interest:
Patent-level drug utilization analyses will include new users of selected medicinal products registered in the respective databases between 1st of January 2014 and 31st of December 2023.
Patients need to have at least 1 year of data visibility prior to the index date, and no use of the respective medicinal products in the previous 1 year.
This requirement of at least 1 year of prior data history will not hold for children < 1 year of age.

Age groups

All
Paediatric Population (< 18 years)
Preterm newborn infants (0 – 27 days)
Term newborn infants (0 – 27 days)
Infants and toddlers (28 days – 23 months)
Children (2 to < 12 years)
Adolescents (12 to < 18 years)
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)

Study design details

Setting

This study will be conducted using routinely collected data from 2 databases in 2 EU countries. All databases were previously mapped to the OMOP Common Data Model (CDM).

1. Integrated Primary Care Information Project (IPCI), the Netherlands
2. IQVIA Disease Analyzer Germany (IQVIA DA Germany), Germany

Documents

Study report

DARWIN EU_Report_P3-C1-006_DUS_Cannabis flos_V5.pdf(1.78 MB)

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)

Integrated Primary Care Information (IPCI)

IQVIA Disease Analyzer Germany

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Not applicable