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

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Study | Planned

Administrative details

PURI
https://redirect.ema.europa.eu/resource/1000000228

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
Planned

Research institution and networks

Institutions

Real-World-Evidence, IQVIA NL
Netherlands
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Institution **ENCePP partner** **Other**

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)
Belgium
Croatia
Denmark
Estonia
Finland
France
Germany
Hungary
Netherlands

Norway
Portugal
Spain
United Kingdom
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Network

Contact details

Study institution contact
Ilse Schuemie
Study contact

study@darwin-eu.org
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

Sources of funding

- EMA

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 topic, other:
Cannabis flos

Study type:
Non-interventional study

Scope of the study:
Drug utilisation

Data collection methods:
Secondary data collection

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 sativa L.

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

Data management

Data sources

Data source(s)
IPCI
Disease Analyzer Germany

Use of a Common Data Model (CDM)

CDM mapping
Yes

Data quality specifications

Check conformance
Unknown

Check completeness
Unknown

Check stability
Unknown

Check logical consistency
Unknown

Data characterisation

Data characterisation conducted
Not applicable