DARWIN EU® - Drug utilisation study on medicinal use of Pelargonii radix

First published: 13/05/2024

Last updated: 27/11/2024

Study Finalised

Administrative details

EU PAS number

EUPAS1000000150

Study ID

1000000150

DARWIN EU® study

Yes

Study countries

Belgium

Germany

Study description

Pelargonii radix is an herbal preparation that has received market authorisation in some European member states for 30 years. It is used for the management of

common cold and acute bronchitis, however further information is needed regarding its real-world use in different age groups, especially in the younger population of children under 12 years old.

Research question
What is the real-world use of Pelargonii radix in children, adolescents, adults and elderly populations?

Study objectives
1. To characterise the cohort of patients being treated with Pelargonii radix at the time of each treatment initiation of the drug of interest in terms of demographics and indication for prescribing/dispensing. Additionally, to determine dose/strength at the treatment initiation, duration of treatment episodes and number of prescriptions of the drug of interest per treatment episode. All results will be stratified by age category (below 3; 3-5; 6-11; 12-17; 18-65, >65 years) and database.
2. To determine incidence of use of Pelargonii radix among different age categories (below 3; 3-5; 6-11; 12-17; 18-65, >65 years) by country/database, during the study period (2014-2023).

Population
Patient-level utilisation of selected medicines of interest

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

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution | Educational Institution | 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

First published: 01/02/2024

Last updated: 30/04/2025

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: 04/03/2024

Actual: 04/03/2024

Study start date
Planned: 08/05/2024

Actual: 08/05/2024

Date of final study report
Planned: 28/06/2024

Actual: 01/08/2024

Sources of funding

- EMA

Study protocol

DARWIN EU_D2.2.3_Protocol_P3-C1-002_DUS_Pelargonium radix_v3.1_Public.pdf
(780.87 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 topic:

Herbal medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Study design:

• New drug user cohort study (Objective 1)

• Population-level cohort study (Objectives 2)

Main study objective:

1. To characterise the cohort of patients being treated with Pelargonii radix at the time of each treatment initiation of the drug of interest in terms of demographics and indication for prescribing/dispensing. Additionally, to determine dose/strength at the treatment initiation, duration of treatment episodes and number of prescriptions of the drug of interest per treatment episode. All results will be stratified by age category (below 3; 3-5; 6-11; 12-17; 18-65, >65 years) and database. 2. To determine incidence of use of Pelargonii radix among different age categories (below 3; 3-5; 611; 12-17; 18-65, >65 years) by country/database, during the study period (2014-2023).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Pelargonii radix

Additional medical condition(s)

Common cold and acute bronchitis

Population studied

Short description of the study population

Patient-level utilisation of selected medicines of interest: Patient-level drug utilisation analyses will include all treatment initiations of pre-specified medicines of interest in the period between 1st of January 2014 and 31st of December 2023. Patients need to have at least 365 days of data visibility prior to the date of their first prescription/dispensing and no use of the respective medication of interest in the previous 30 days. This requirement of at least 1 year of prior data history will not hold for children <1 year of age.

Population-level utilisation of selected medicines of interest: Population-level drug utilisation analyses will include all individuals registered in the database between 1st of January 2014 and 31st of December 2023, with at least 365 days of data visibility prior to 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.

Age groups

- **Paediatric Population (< 18 years)**
  - 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

Data analysis plan

Patient-level utilisation of selected medicines of interest: Patient level characterisation will be conducted at index date. Index date will be the date at time of first prescription of each new treatment episode of the drug of interest for each person. The frequency of indication of drug use will be assessed by searching for predefined disease categories. Additionally, top 10 SNOMED codes reported in window around index date will be determined. Initial dose/strength will be estimated, and the minimum, quartiles and maximum values will be provided. Duration of treatment episodes will be calculated and summarized providing the minimum, quartiles, and maximum duration of treatment episodes. Number of prescriptions per treatment episode will be estimated and minimum, quartiles and maximum number of repeated prescriptions of the index drug will be reported. The statistical analyses will be conducted using the “DrugUtilization” R Package based on OMOPCDM mapped data and will be stratified by age category (below 3; 3-5; 6-11; 12-17; 18-65, >65 years) and database.

Population-level utilisation of selected medicines of interest: Incidence rate of use of medicines of interests, expressed as numbers of treatment initiations per

person-year, will be estimated in separate age categories (below 3; 3-5; 6-11; 12-17; 18-65, >65 years) (Objective 2). The statistical analyses will be performed based on OMOP-CDM mapped data using “IncidencePrevalence” R package.

For all analyses a minimum cell counts of 5 will be used when reporting results, with any smaller counts obscured.

Documents

Study report

DARWIN EU_Report_P3-C1-002_DUS_Pelargonium_radix_V5.pdf (1.17 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)

IQVIA Disease Analyzer Germany

IQVIA Longitudinal Patient Data - Belgium

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

No