DARWIN EU® - DUS Characterising STOPP criteria medication use in people with recurrent falls

First published: 18/10/2024

Last updated: 28/04/2025

Study Finalised

Administrative details

EU PAS number

EUPAS1000000333

Study ID

1000000333

DARWIN EU® study

Yes

Study countries

- [ ] Croatia
- [ ] Finland
- [ ] Germany
- [ ] Spain

United Kingdom

Study description

Falls in older adults are associated with significant health outcomes, including hospitalization and increased mortality. Inappropriate prescribing, particularly in populations with multimorbidity and polypharmacy, is a recognized risk factor for falls. The prevalence of potentially inappropriate prescriptions, as outlined in Section K of the STOPP criteria, among individuals with recurrent falls remains uncertain across Europe.

Study status

Finalised

Research institutions and networks

Institutions

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: 08/07/2024

Actual: 08/07/2024

Study start date

Planned: 01/10/2024

Actual: 01/10/2024

Date of final study report

Planned: 31/01/2025

Actual: 17/04/2025

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P3-C1-011_DUS_STOPP criteria medication_V2.pdf (1.07 MB)

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:

Disease /health condition

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 5 databases.

Main study objective:

Research question: What are the characteristics of patients with recurrent falls and how are STOPP Section K criteria medicines prescribed in Europe?

Study objectives:

1. To characterise individuals aged 65 years and older with recurrent falls in terms of age, gender, risk factors, comorbidities and concomitant prescriptions. Results will be stratified by database and where feasible by healthcare setting.
2. To estimate the overall survival of individuals aged 65 and older with recurrent falls.
3. To estimate prevalence of use of drug classes belonging to the STOPP section K criteria in individuals aged 65 and older, categorised into two cohorts: those with recurrent falls and those without recurrent falls. Results will be stratified by database, calendar year, age and sex.
4. To estimate incidence of use of drug classes belonging to the STOPP section K criteria in individuals aged 65 year and older, categorised into two cohorts: those with recurrent falls and those without recurrent falls. Results will be stratified by database, calendar year, age and sex.
5. To characterise a cohort of individuals aged 65 years and older with recurrent falls at time of their new prescription of any of the drug classes belonging to the STOPP section K criteria in terms of age, sex, comorbidities and comedication. Additionally, the proportion of individual drug substances within each drug class belonging to the STOPP section K criteria will be provided. Results will be stratified by database.

6. To determine the median duration of use the different drug classes belonging to the STOPP section K criteria at time of treatment initiation of drugs of interest in the individuals aged 65 and older, categorised into two cohorts: those with recurrent falls and those without recurrent falls. To provide product names with details on strength, formulation and volume.

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

The study cohort will include individuals aged 65 years and older diagnosed with recurrent falls registered in the respective databases between 1st of January 2013 and 31st December 2023, with at least 1 year of data visibility prior to the date of recurrent falls diagnosis. Recurrent falls will be defined as 2 or more falls within a period of 12 months.
Additional eligibility criteria will be applied for survival analysis: a minimum of 1 year of potential follow-up after index date, will be applied for survival analysis.

Age groups

- Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Documents

Study report

DARWIN EU_Report_P3-C1-011_STOPP Criteria_V3.pdf (11.25 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)

Clinical Practice Research Datalink (CPRD) GOLD

Croatia National Public Health Information System (Nacionalni javnozdravstveni informacijski sustav)

IQVIA Disease Analyzer Germany

The Information System for Research in Primary Care (SIDIAP)

Terveydenhuollon hoitoilmoitusrekisteri (Finland Care Register for Health Care)

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

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

CDM version

https://ohdsi.github.io/CommonDataModel/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown