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

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Administrative details

EU PAS number	
EUPAS1000000333	
Study ID	
100000333	
DARWIN EU® study	
Yes	
Study countries Croatia Finland Germany Spain	

United	Kingdom
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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

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: 08/07/2024

Actual: 08/07/2024

Study start date

Planned: 01/10/2024

Actual: 01/10/2024

Date of final study report

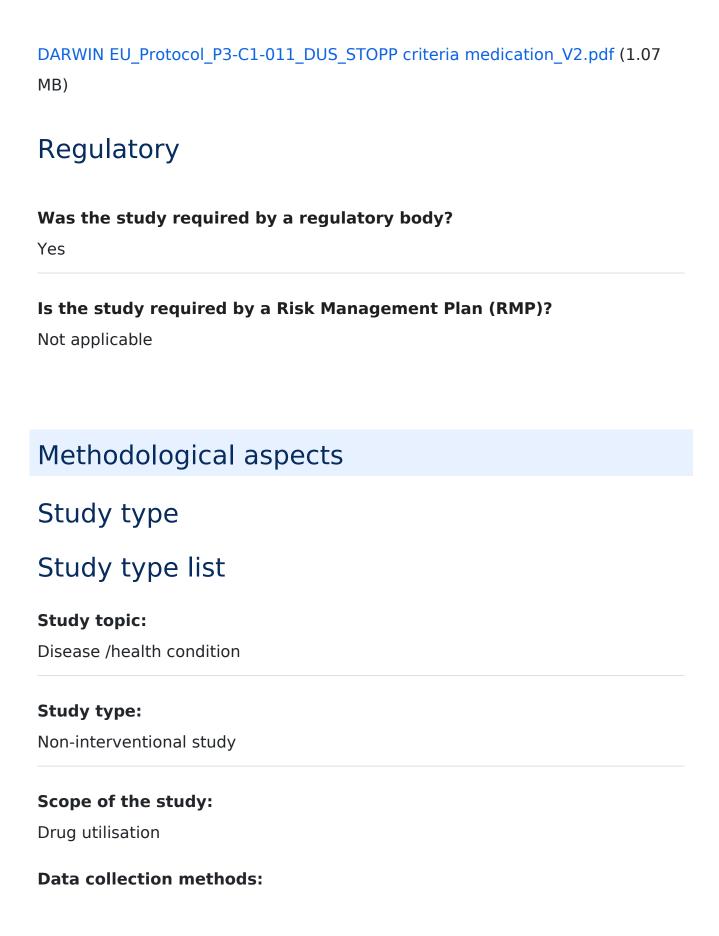
Planned: 31/01/2025

Actual: 17/04/2025

Sources of funding

EMA

Study protocol



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