Incidence, prevalence, and characterisation of medicines with suggested drug shortages in Europe

First published: 02/10/2023

Last updated: 22/02/2024

Study Planned

Administrative details

EU PAS number

EUPAS106954

Study ID

107398

DARWIN EU® study

No

Study countries

- ☐ Belgium
- ☐ Bulgaria
- ☐ Denmark
- ☐ Estonia

- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Montenegro
- [ ] Netherlands
- [ ] Portugal
- [ ] Serbia
- [ ] Spain
- [ ] Türkiye
- [ ] United Kingdom

Study description

This study aims to characterise the incidence and prevalence of medicines with (suggested) shortages and their alternatives for the period 2010-2023, stratified by healthcare setting and time period in each database. Furthermore, we aim to describe incident and prevalent patients receiving a prescription / dispensation of a medicine with (suggested) shortages for the period 2010-2023, stratified by year in each database, including information on potential indication, treatment duration, and dosage.

Study status

Planned

Research institutions and networks

Institutions

Pharmaco- and Device epidemiology, University of Oxford

United Kingdom

First published: 12/09/2023

Last updated: 11/07/2024

Institution | Educational Institution | ENCePP partner

Networks

European Health Data Evidence Network (EHDEN)

Netherlands

First published: 01/02/2024

Last updated: 11/06/2024

Network

Contact details

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Primary lead investigator

Daniel Prieto-Alhambra

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/11/2018

Study start date
Planned: 01/01/2010

Date of final study report
Planned: 30/09/2024

Sources of funding

- Other

More details on funding

EHDEN

Study protocol

EHDENMegaStudy_drugshortage v1.0_FINAL.pdf(950.09 KB)

EHDENMegaStudy_drugshortage v2.0_FINAL.pdf(950.92 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Main study objective:

To investigate the incidence and prevalence of use of medicines with (suggested) shortages and their alternatives stratified by annual period (calendar year) and healthcare setting for each database during the study period 2010-2023, and to characterize the patients and the use of medicines regarding potential indication, treatment duration, and dosage.

Study Design

Non-interventional study design

Other

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AD11) tenecteplase

tenecteplase

(L04AC14) sarilumab

sarilumab

Population studied

Age groups

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)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

200000

Study design details

Outcomes

To investigate the incidence and prevalence of use of medicines with (suggested) shortages and their alternatives stratified by annual period

(calendar year) and healthcare setting for each database during the study period 2010-2023. To characterise the patients and the use of medicines regarding potential indication, treatment duration, and dosage.

Data analysis plan

Population-level drug utilisation study: annual period prevalence of the medicine use and annual incidence proportion. Patient-level drug utilisation study: Large-scale patient-level characterisation will be conducted in incident and in prevalent users, defined as follows: I) in incident users, the index date will be the date of a prescription qualifying as a "new prescription" (i.e. after at least 30 days of non-use) of the specific medicine of interest for each person, II) the index date in prevalent users will be the earliest date of a prescription in the calendar year. Frequency of potential indication at index date will be assessed. Treatment duration will be estimated and the minimum, p25, median, p75, and maximum will be provided. Furthermore, daily dosage will be estimated and the minimum, p25, median, p75, and maximum will be provided.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Integrated Primary Care Information (IPCI)

Institut Municipal d'Assistència Sanitària Information System

The Information System for Research in Primary Care (SIDIAP)

Data source(s), other

LPD France

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No