DARWIN EU® DUS of Antibiotics in the ‘Watch’ category of the WHO AWaRe classification of antibiotics for evaluation and monitoring of use

First published: 03/02/2023

Last updated: 25/09/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/103382

EU PAS number

EUPAS103381

Study ID

103382

DARWIN EU® study

Yes

Study countries

- [ ] France
- [ ] Germany
- [ ] Netherlands
- [ ] Spain
- [ ] United Kingdom

Study description

This drug utilisation study aims to characterise the incidence of prescription of the 141 antibiotics in the ‘Watch’ list, including indication and treatment duration, for the period 2012-2021, stratified by year and country. For this study, databases from 5 European countries will be used namely IPCI (Nl), CPRD Gold (UK), SIDIAP (Spain), IQVIA DA (Germany), IMASIS (Spain) and CHUBX (France). Specific objectives of this study are the following: (i) To investigate the incidence and prevalence of use of antibiotics (from the WHO Watch list) stratified by calendar year, age, sex and country/database during the study period 2012-2021. (ii) To explore duration of antibiotic use as well as indication for antibiotic prescribing/dispensing.

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

IQVIA NL, Real-World-Evidence

Netherlands

First published: 25/11/2022

Last updated: 21/03/2025

Institution | Other | ENCePP partner

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain

First published: 05/10/2012

Last updated: 23/02/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

PSMAR Spain, CHUBX France, University of Oxford UK

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

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Study contact

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Primary lead investigator

Katia Verhamme

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/11/2022

Actual: 03/11/2022

Study start date

Planned: 01/12/2022

Actual: 01/12/2021

Data analysis start date

Planned: 02/01/2023

Actual: 02/01/2023

Date of final study report

Planned: 06/02/2023

Actual: 15/02/2023

Sources of funding

- EMA

Study protocol

D2.2.3_Darwin_EU_Study_Protocol_C1-003_v2.2.pdf(970.76 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 type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To investigate the incidence and prevalence of use of antibiotics (from the WHO Watch list) stratified by calendar year, age, sex and country/database during the study period 2012-2021. To explore duration of antibiotic use as well as indication for antibiotic prescribing/dispensing.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J01A) TETRACYCLINES

TETRACYCLINES

(J01C) BETA-LACTAM ANTIBACTERIALS, PENICILLINS

BETA-LACTAM ANTIBACTERIALS, PENICILLINS

(J01DD) Third-generation cephalosporins

Third-generation cephalosporins

(J01F) MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

(J01G) AMINOGLYCOSIDE ANTIBACTERIALS

AMINOGLYCOSIDE ANTIBACTERIALS

(J01MB) Other quinolones

Other quinolones

(J01XX) Other antibacterials

Other antibacterials

Population studied

Short description of the study population

The study focused on population-level drug utilisation of antibiotics and patient-level drug utilisation analysis.

The population-level analysis includes individuals with 365 days of database history between 1 January 2012 and 31 December 2021, examining the prevalence and incidence of antibiotic use.

The patient-level analysis includes new users of antibiotics who have not used the antibiotic for 30 days between 1 January 2012 and 31 December 2021, with at least 365 days of visibility prior to their first antibiotic prescription/dispensing.

Age groups

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

30000000

Study design details

Data analysis plan

Population-level antibiotic use: Annual period prevalence of antibiotic use and annual incidence rates per 100,000 person years. Patient-level antibiotic use: Large-scale patient-level characterisation will be conducted. Index date will be the date of the first prescription of the specific antibiotic for each person. Frequency of indication at index date will be assessed. Cumulative treatment duration will be estimated and the minimum, p25, median, p75, and maximum will be provided. For all analyses a minimum cell count of 5 will be used when reporting results, with any smaller counts obscured.

Documents

Study results

StudyReport_C1-003_version3.1.pdf(4.2 MB)

Study report

Appendix_StudyReport_C1-003_v3.1.pdf(1.14 MB)

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

The Information System for Research in Primary Care (SIDIAP)

Integrated Primary Care Information (IPCI)

IQVIA Disease Analyzer Germany

Institut Municipal d'Assistència Sanitària Information System

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Data source(s), other

CHUBX France

Data sources (types)

Electronic healthcare records (EHR)

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