EMIF Use Case 17 - Investigating the relationship in paediatric population between dosing of antibiotics (prescribed, dispensed or administered) and patient's weight. (EMIF UC17)

First published: 20/06/2018

Last updated: 31/01/2019

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/27797

EU PAS number

EUPAS24458

Study ID

27797

DARWIN EU® study

No

Study countries

- [ ] Italy
- [ ] Netherlands
- [ ] Spain

Study description

Dosing errors are one of the most common types of medication issues and contribute to themortality and morbidity within the paediatric population. Paediatric patients are at a higher riskthan adults of experiencing such problems because of the need for a dose calculation based onthe patient’s age, weight (mg/kg), body surface area (mg/m 2), and clinical condition.Antibiotics are the medications most widely prescribed in the paediatric population and one of thedrug classes most commonly reported to be involved in paediatric dosing errors.Despite a number of studies conducted about antibiotics usage in different European countries,the appropriateness of antibiotic dosing (prescribed by doctors in primary or secondary care,dispensed by community or hospital pharmacies, or administered in hospital settings) according tothe child’s age, weight and height (and other related parameters, as Body Mass Index - BMI, BodySurface Area - BSA) has not yet been investigated.In this study, we would like to assess in European Medical Information Framework (EMIF)Electronic Healthcare Records (EHR) databases (DBs) the relationship between dosing ofantibiotics prescribed, administered or dispensed (either for outpatients or inpatient settings) tochildren (age 0-18 yr), and their weight, age and height.

Study status

Ongoing

Research institutions and networks

Institutions

So.Se.Te

First published: 01/02/2024

Last updated: 01/02/2024

Institution

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands

First published: 07/01/2022

Last updated: 24/07/2024

Institution | Laboratory/Research/Testing facility | ENCePP partner

Pedianet network

Italy

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Other

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

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

PHARMO Netherlands, Pedianet Italy, SIDIAP Spain, IPCI Netherlands

Networks

European Medical Information Framework (EMIF)

European Union

First published: 01/02/2024

Last updated: 12/03/2024

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Luigi Cantarutti

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 11/12/2012

Actual: 11/12/2012

Study start date

Planned: 15/06/2018

Actual: 28/06/2018

Data analysis start date
Planned: 03/12/2018

Actual: 03/12/2018

Date of final study report
Planned: 31/07/2019

Sources of funding

- Other

More details on funding

EU/EFPIA

Study protocol

PediatricUseCase_UC17.pdf(1.12 MB)

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

Scope of the study:

Drug utilisation

Main study objective:

The primary objective is to investigate for each DB, the relationship,among the Drug Events, between the antibiotic dosing and the patient’s weight, stratified by:• type of antibiotic (ATC code),• care setting (Hospitalisation/No-Hospitalisation)

Study Design

Non-interventional study design

Other

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J01CA04) amoxicillin

amoxicillin

(J01CR02) amoxicillin and beta-lactamase inhibitor

amoxicillin and beta-lactamase inhibitor

(J01CE02) phenoxymethylpenicillin

phenoxymethylpenicillin

(J01CE05) pheneticillin

pheneticillin

(J01CF05) flucloxacillin

flucloxacillin

(J01DC04) cefaclor

cefaclor

(J01FA01) erythromycin

erythromycin

(J01FA10) azithromycin

azithromycin

(J01FA09) clarithromycin

clarithromycin

(J01CA01) ampicillin

ampicillin

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)

Estimated number of subjects

3000000

Study design details

Outcomes

The primary objective is to investigate, for each DB, the relationshipamong the Drug Events, between the antibiotic dosing and the patient’s weight, stratified

by:• type of antibiotic (ATC code),• care setting (Hospitalisation/No-Hospitalisation), The first secondary objective is to evaluate the frequency distribution of the different types of antibiotics in all DEs, stratified, for each DB, by:• care setting (Hospitalisation/No-Hospitalisation),• calendar year,• age group.The second secondary objective is to investigate, for each DB, the relationshipamong the Drug Events, between the antibiotic dosing and the patient’s BSA

Data analysis plan

Data extraction, transformation, derivation of specific variables will be done locally at each site by data custodians, using purpose-build software called Jerboa Reloaded. The results are transmitted to a central secured environment, namely, a Private Remote Research Environment (PRRE), for further processing and analyses. Since we expect a linear correlation, among the DEs, between the antibiotic dosing (expressed as mg/day) and the patient’s weight (expressed in kilos), this relationship will be investigated scatter-plotting the antibiotic dosing against the patient's weight and computing Pearson's correlation coefficient r.

Data management

Data sources

Data source(s)

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

PHARMO Data Network

ARS Toscana

Pedianet network

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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