PATTERN OF USE AND SAFETY PROFILE OF BRANDED VS GENERIC ANTIEPILEPTIC DRUGS

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Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/44414

EU PAS number
EUPAS24224

Study ID
44414

DARWIN EU® study
No

Study countries
Italy

Study status
Finalised

Research institution and networks

Institutions

Unit of adverse drug reactions monitoring (UADRM), University Hospital of Pisa

Italy
First published: 08/01/2014
Last updated
16/02/2024

Institution
Hospital/Clinic/Other health care facility
Educational Institution
ENCePP partner

Neurofarba Department, Pharmacovigilance Unit, University of Florence

Italy
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Institution
ENCePP partner
Educational Institution

Unit of adverse drug reactions monitoring (UADRM), University Hospital of Pisa

Italy
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Institution
Hospital/Clinic/Other health care facility
Educational Institution
ENCePP partner

Contact details

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Primary lead investigator
Ersilia Lucenteforte
Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
01/06/2018
Actual:
01/06/2018

Study start date
Planned:
01/06/2018
Actual:
01/06/2018

Data analysis start date
Planned:
11/06/2018

Date of final study report
Planned:
28/09/2018
Actual:
18/02/2021

Sources of funding

- Other

More details on funding

University of Florence

Study protocol

Project AEDs.pdf(439.31 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 topic:
Human medicinal product

Study type:
Non-interventional study

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness
Drug utilisation

Data collection methods:
Secondary data collection

Main study objective:
- describe the therapeutic pattern of generic vs branded antiepileptics (AEDs). - assess the risk profile of generic vs branded AEDs . -to describe the most frequent AEDs- related ADRs among users of generic vs branded AEDs.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(N03) ANTIEPILEPTICS

Population studied

Short description of the study population
The source population corresponds to all subjects active into the database at January the 1, 2015 and that, at this date, had at least 365 days of look-back period. Within such population, all subjects with ?1 prescription of any AEDs (ATC: N03*) will be identified. For each subject, the first AED prescription (ATC: N03*) in the study period will be considered as the index prescription, and its date will be considered as the index date.
Subjects prescribed with AEDs in the 12 months before the index date (look-back period) will be excluded. In addition, we will exclude all subjects with active neoplasia or with history of neoplasia, identified as presence of prescription records and/or hospitalizations related to neoplasia during the look-back (i.e. use of antineoplastic drug (ATC: L01*), and/or hospital discharge records with a diagnosis of neoplasia (ICD-9-CM codes: 140*-208*; 230*-239*) in primary or secondary diagnosis field).

Age groups
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)

Special population of interest
Hepatic impaired
Immunocompromised
Pregnant women
Renal impaired

Estimated number of subjects
30000

Study design details

Outcomes
All hospitalization and/or access to ED occurring during follow-up. All hospitalization and/or access to ED occurring during follow-up with a diagnosis of possible AEDs-related ADRs in primary or secondary diagnosis field.

Data analysis plan
- Descriptive analysis will be used to describe the most frequently prescribed active principles and exposure classes, proportions of switching, and the most frequent AEDs-related ADRs. - Propensity Score (PS) calculation: we will use PS matching to balance the baseline characteristics between subjects treated with brand vs generic AEDs. PS will be calculated on demographic, socio-economic and clinical variables, using the Stata routine PSmatch2 to perform nearest number matching with a caliper of 0.2. of the SD of PS. - Statistical analysis: Adjusted Cox regression models will be fitted to estimate the risk of hospitalization and/or access to ED for any cause and for AEDs-related ADRs among subjects exposed to generic vs branded AEDs. Analysis will be stratified according to different ATC codes.

Documents

Study, other information
EUPAS24224_publication.pdf(35.31 KB)

Data management

Data sources

Data source(s)
ARS Toscana

Data sources (types)
Administrative data (e.g. claims)

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