Pharmacoepidemiological Safety Study of Neuroleptics and Antidepressants in the Area of Geriatric Psychiatrics (PhaSiNAg)

First published: 14/05/2014
Last updated: 02/07/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/29000

EU PAS number
EUPAS6539

Study ID
29000

DARWIN EU® study
No

Study countries
Germany

Study description
The use of neuroleptics and antidepressants in elderly patients has been associated with adverse drug reactions such as cerebrovascular and cardiovascular events, pneumonia, fractures, venous thromboembolism and higher all-cause mortality. Based on data from the German Pharmacoepidemiological Research Database (GePaRD), the PhaSINAg project will investigate the safety profiles of neuroleptics and antidepressants in elderly patients in consideration of co-morbidity and co-medication.. Furthermore, prescription patterns of neuroleptics and antidepressants in patients aged 65 years and older will be analyzed. Within this context, investigations on how previous risk minimization activities led to

changes in prescription patterns and how administrative data may be used for systematic risk monitoring will be conducted.

Study status
Finalised

Research institution and networks

Institutions

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany
First published: 29/03/2010
Last updated
26/02/2024

Institution

ENCePP partner

Not-for-profit

Contact details

Study institution contact
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Study contact

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Primary lead investigator
Tania Schink

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
02/10/2012
Actual:
02/10/2012

Study start date
Planned:
01/01/2004
Actual:
01/01/2004

Date of final study report
Planned:
31/10/2014
Actual:
19/12/2014

Sources of funding

- Other

More details on funding

Federal Institute for Drugs and Medical Devices, Insitute funds

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:
Disease /health condition

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:
To estimate the risk of acute myocardial infarction, heart failure, ventricular arrhythmia, ischemic stroke, hip fracture and all-cause mortality for incident users of NLs and ADs aged 65 years and older and to compare these risks between individual drugs and drug classes. For incident NL users, the outcomes pneumonia and venous thromboembolism will also be investigated.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(N05A) ANTIPSYCHOTICS
(N06A) ANTIDEPRESSANTS

Medical condition to be studied
Ventricular arrhythmia
Cardiac failure
Pneumonia
Ischaemic stroke
Hip fracture
Death
Embolism venous

Population studied

Short description of the study population
neuroleptics (NLs) and antidepressants (ADs) users aged 65 years and older.

Age groups
Adults (65 to < 75 years)
Adults (75 to < 85 years)
Adults (85 years and over)

Estimated number of subjects
523000

Study design details

Outcomes
Acute myocardial infarction, heart failure, ventricular arrhythmia, ischemic stroke, hip fracture, pneumonia, venous thromboembolism and all-cause mortality.

Data analysis plan
For the primary and secondary analysis, Cox models will be used to estimate the adjusted hazard ratio for each outcome in the NL (reference group: atypical neuroleptic) and antidepressant (reference group: tri- and tetracyclic antidepressants) drug classes and for frequently used individual drugs (reference group neuroleptic: risperidone, reference group antidepressants: citalopram). The time-scale for the time-to-event analysis is the time in the cohort until occurrence of an outcome or censoring at the end of cohort time. Pre-defined a priori covariates such as age, sex, and prior history of selected co-morbidity and co-medication will always be included in the model. A backward selection (p=0.05) will be performed to include additional covariates in the model.

Documents

Study results
Final Scientific Report_PhaSiNAg_v1.0_FINAL.pdf(1.59 MB)

Study publications
Jobski, K., Schmedt, N., Kollhorst, B. et al. Characteristics and drug use patt…
Schmedt N, Kollhorst B, Enders D, Jobski K, Krappweis J, Garbe E, Schink T. Com…
Schmedt N, Jobski K, Kollhorst B, Krappweis J, Rüther E, Schink T, Garbe E. Tre…
Pisa FE, Reinold J, Kollhorst B, Haug U, Schink T. Antidepressants and the risk…

Data management

Data sources

Data source(s)
German Pharmacoepidemiological Research Database

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
Unknown