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

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 institutions and networks

Institutions

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany

First published: 29/03/2010

Last updated: 26/02/2024

Institution **Not-for-profit** **ENCePP partner**

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 use of data

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

ANTIPSYCHOTICS

(N06A) ANTIDEPRESSANTS

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

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

German Pharmacoepidemiological Research Database

Data sources (types)

Administrative healthcare records (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