

Pharmacovigilance in gerontopsychiatric patients (GAP)

First published: 16/05/2013

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Study

Ongoing

Administrative details

EU PAS number

EUPAS3953

Study ID

4170

DARWIN EU® study

No

Study countries

 Germany

Study description

The purpose of this observational multicenter-study is to investigate safety of psychopharmacological treatment and rates of adverse drug reactions in gerontopsychiatric inpatients. Elderly people are at higher risk for developing

side effects under pharmacological treatment due to an altered metabolic situation, higher comorbidity rates and often polypharmacy. Furthermore gerontopsychiatric patients can often not articulate their symptoms clearly, for example due to pronounced cognitive impairment. The aim of the study is to gain valid data of possible adverse drug reaction rates, their potential risk factors and outcome, as well as medical prescription practises. To assess these outcomes an intensive pharmacovigilance-monitoring will be conducted at the five participating study sites. At Baseline demographic data, previous and present disorders, use of drugs, previous and present medication, quality of life, cognitive function, physical examination results, laboratory results and ECG will be assessed. Afterwards patients are visited weekly and screened for possible adverse drug reactions. All adverse drug reactions will be coded in the MedDRA-system. In case of a possible serious adverse drug reaction serum levels of all psychotropic substances applied will be assessed. Drug combinations will be analysed using an established advanced bioinformatic tool (mediQ). Diagnosis, medication intake and possible adverse drug reactions are documented continually. 2 weeks after discharge from the ward, patients will be contacted by phone to assess catamnestic data.

Study status

Ongoing

Research institutions and networks

Institutions

[Hannover Medical School \(MHH\)](#)

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Institution


Educational Institution


Hospital/Clinic/Other health care facility


Asklepios Fachklinikum Teupitz Teupitz, Germany,
Asklepios Fachklinikum Lübben Lübben, Germany,
Asklepios Fachklinikum Brandenburg Brandenburg
an der Havel, Germany, Krankenhaus
Hedwigshöhe Berlin, Germany, Medizinische
Hochschule Hannover Hannover, Germany

Networks

AMSP Network (AMSP)

 Austria

 Germany

 Switzerland

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Last updated: 20/08/2024

Network

Kompetenznetz TDM KJP e.V.

Contact details

Study institution contact

Alexandra Kleimann kleimann.alexandra@mh-hannover.de

Study contact

kleimann.alexandra@mh-hannover.de

Primary lead investigator

Helge Frieling

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 24/10/2012

Study start date

Planned: 21/05/2013

Actual: 21/05/2013

Data analysis start date

Planned: 15/05/2015

Date of final study report

Planned: 31/12/2015

Sources of funding

- Other

More details on funding

Federal Institute for Drugs and Medical Devices, Hannover Medical School

Regulatory

Was the study required by a regulatory body?

Unknown

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Other

If 'other', further details on the scope of the study

Pharmacovigilance

Main study objective:

The purpose of this observational multicenter-study is to investigate safety of psychopharmacological treatment and rates of adverse drug reactions in gerontopsychiatric inpatients. We also aim to validate a rating-scale for adverse events in geriatric psychiatric patients(GAERS) and analyse special risk factor combinations in elderly patients to develop risk management plans.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Intensive monitoring schemes, pharmacokinetic study, pharmacodynamic study, drug interaction study

Population studied

Age groups

- Adults (65 to < 75 years)
 - Adults (75 to < 85 years)
 - Adults (85 years and over)
-

Estimated number of subjects

4000

Study design details

Outcomes

Assessment of frequency and severity of adverse events in geriatric psychiatry inpatients under psychopharmacological treatment, - demographic data- laboratory results, ECG, physical examination- Assessment of cognitive functioning- Quality of life - Adverse drug reactions- serum levels of substances- drug combination analysis

Data analysis plan

With bivariate analysis procedures (for example univariate logistic regression) impact of different drug combinations on frequency of possible adverse drug reaction will be analysed. To develop risk-scores (demographic data, previous disorders, etc.) multivariate logistic regression modelling respectively Cox-regression and backward selection (using Akaike information criterion (AIC) and Bayesian information criterion), alternatively Classification and Regression Tree Analysis (CART) will be used. For validation of risk models cross-validation technique and bootstrapping will be used.

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 sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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