Pharmacovigilance in gerontopsychiatric patients (GAP)

First published: 16/05/2013

Last updated: 21/06/2013

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/4170

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 applicated 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)

First published: 01/02/2024

Last updated: 01/02/2024

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

First published: 08/02/2010

Last updated: 20/08/2024

Network

Kompetenznetz TDM KJP e.V.

Contact details

Study institution contact

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Study contact

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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 eldery patients to develop risk managment 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 univariat logistic regression) impact of different drug combinations on frequency of possbile 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 modells cross-validation technique and bootstrapping will be used.

Data management

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