

# Pharmacovigilance in gerontopsychiatric patients (GAP)

**First published:** 16/05/2013

**Last updated:** 21/06/2013

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS3953

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### Study ID

4170

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### DARWIN EU® study

No

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### Study countries

Germany

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### 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.

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### **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

**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

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### Study start date

Planned: 21/05/2013

Actual: 21/05/2013

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### Data analysis start date

Planned: 15/05/2015

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### 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

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#### **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

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### **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)
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### **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

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## 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

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### **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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## **Data characterisation**

### **Data characterisation conducted**

No