

## Trial Description

### Title

**Polypharmacy as a result of multiple chronic conditions of older people: rational therapy with the new FORTA classification?**

### Trial Acronym

[---]\*

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**Polypharmacy, overtreatment, and undertreatment with drugs are frequent in older subjects. Since there are no guidelines for the management of this problem, the newly developed FORTA (fit for the aged) classification was created to support the clinical decision making of pharmacological treatment in old age. However, the FORTA classification was never tested in clinical practice.**

**In the current study, the medication will be reviewed by the criteria of the new FORTA classification in a sample of geriatric in-hospital patients. Treatment will be adjusted then accordingly in one patient group (cluster I). In a second cluster of patients, pharmacological treatment is applied according to good clinical practice. Furthermore, all prevalent diseases were recorded and checked whether they are adequately treated.**

**The aim of the study is to estimate the impact of the application of the FORTA classification on the quality of pharmacological prescription in a sample of older in-hospital patients.**

**A second aim is to identify and quantify pharmacological overtreatment and undertreatment.**

### Brief Summary in Scientific Language

**Cluster randomized study in 400 geriatric clinic patients with review of current medication based on the new FORTA classification, recording of all prevalent diseases and assessing of the need of treatment. Adjustment of the medication according to FORTA in one patient cluster, continuing the medication in the second patient cluster according to the rules of good medical practice.**

**The main outcome of the study is the extent of the effect of applying FORTA on pharmacotherapy by comparing treatments between the two clusters. A second aim is to identify over- and undertreatment of diseases and comparison of the frequencies between both clusters.**

### Do you plan to share individual participant data with other researchers?

[---]\*

### Description IPD sharing plan

[---]\*

## Organizational Data

- DRKS-ID: **DRKS00000531**
- Date of Registration in DRKS: **2010/09/15**
- Date of Registration in Partner Registry or other Primary Registry: [---]\*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2010-273N-MA , Medizinische Ethik-Kommission II  
Medizinische Fakultät Mannheim der Universität Heidelberg**

## Secondary IDs

- Universal Trial Number (UTN): **U1111-1116-6958**

## Health condition or Problem studied

- Free text: **eligible for the study are patients of a geriatric unit with numerous co-morbid conditions.**

## Interventions/Observational Groups

- Arm 1: **Review and adjustment of medication according to the FORTA criteria**
- Arm 2: **Continue the medication according to guidelines and Good Medical Practice**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]\*
- Allocation: **Randomized controlled trial**
- Blinding: **Single blind**
- Who is blinded: **patient/subject**
-

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Allocation: **Randomized controlled trial**

Blinding: **Single blind**

Who is blinded: **patient/subject**

Control: **Active control**

- Purpose: **Health economics**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]\***

### Primary Outcome

**The FORTA classification encompasses four classes of drugs. Drugs with well documented evidence for the elderly constitute the classes A and B, drugs with limited evidence constitute the class C. Drug of the class D should be avoided in the elderly.**

**The aim of the study is the statistical measurement of the difference in the distribution of medication at discharge according to the four classes of FORTA between the two patient groups (clusters).**

### Secondary Outcome

**Statistically comparison of the the two clusters regarding  
Number of untreated disease  
Number of diseases overtreated**

### Countries of recruitment

- **DE Germany**

### Locations of Recruitment

### Recruitment

- Planned/Actual: **Actual**

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- (Anticipated or Actual) Date of First Enrollment: **2011/11/28**
- Target Sample Size: **400**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

#### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **65 Years**
- Maximum Age: **100 Years**

#### Additional Inclusion Criteria

**informed consent given,  
stable clinical condition,  
no palliative condition**

#### Exclusion criteria

**missing informed consent,  
palliative clinical condition,  
unstable clinical condition,  
need of intensive care unit (ICU) treatment**

#### Addresses

##### ■ Primary Sponsor

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##### ■ Contact for Scientific Queries

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### ■ **Contact for Public Queries**

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### ■ **Secondary Sponsor**

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## **Sources of Monetary or Material Support**

### ■ **Institutional budget, no external funding (budget of sponsor/PI)**

**Institut für klinische Pharmakologie Mannheim  
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- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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E-mail: [---]\*

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## Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]\*

## Trial Publications, Results and other documents

- Paper **Frohnhofen H, Michalek C, Wehling M. Assessment of drug treatment in geriatrics with the new FORTA criteria Dtsch Med Wschr 2011; 136(27): 1417-1421**

\* This entry means the parameter is not applicable or has not been set.

\*\*\* This entry means that data is not displayed due to insufficient data privacy clearing.