

Trial Description

Title

Dementia and delirium in the general hospital: prevalence and care

Trial Acronym

GHoSt

URL of the trial

[---]*

Brief Summary in Lay Language

With the rising incidence of dementia, the number of older general hospital patients suffering from dementia is steadily increasing. Yet, the number of patients with dementia in general hospitals cannot be quantified precisely. Estimates from empirical studies range from 3% to 45% and are, therefore, worthless for the provision of care.

Several studies reported that cognitive disorders cause great stress for patients, families, clinics and hospital staff. Hospital stays are prolonged, higher levels of supervision are required and expenditures rise. Moreover, cognitively impaired in-patients face a higher risk of secondary health problems. The long-term prognosis is characterized by elevated mortality, increased need of help and care dependency as well as more admissions to nursing homes. The lack of knowledge about the frequency, distribution and care needs of in-patients with cognitive disorders precludes the improvement of care.

The study has the following objectives:

- Determining the point prevalence of cognitive disorders (dementia and delirium) among a representative sample of in-patients, aged above 65.**
- Describing the distribution of the diseases according to demographic characteristics, medical departments and causes of admission.**
- Differentiating between already diagnosed and yet undiscovered cognitive disorders.**
- Creating an inventory of measures and services that are provided by the hospitals for the (special) care of patients with dementia and delirium.**
- Identifying approaches to improve care of people with dementia or delirium in the hospital.**
- Detecting specific care needs and difficulties.**
- Describing complications, special measures and precautions that were necessary during treatment.**

These objectives are to be achieved by a representative study of more than 1,200 patients aged above 65, who are hospitalized at an appointed date in one of 32 randomly selected general hospitals in Bavaria and Baden-Württemberg. Specialized hospitals are excluded. It is planned that approximately 40 patients per selected hospital will participate. Data collection in each hospital will be completed within one to two weeks. The data collection subdivides into the following four parts: (1) A survey and cognitive performance testing of patients to determine their cognitive status, (2) a documentation of diagnoses, medication

and special treatment arrangements, (3) a survey administered to the nursing staff investigating the effort needed for caring and unique care demands and (4) a data collection at the department level considering special measures and precautions when dealing with cognitively impaired patients.

Brief Summary in Scientific Language

With the rising incidence of dementia, the number of older general hospital patients suffering from dementia is steadily increasing. Yet, the number of patients with dementia in general hospitals cannot be quantified precisely. Estimates from empirical studies range from 3% to 45% and are, therefore, worthless for the provision of care. The lack of knowledge about the frequency, distribution and care needs of in-patients with cognitive disorders precludes the improvement of care.

The study has the following objectives:

- **Determining the point prevalence of cognitive disorders (dementia and delirium) among a representative sample of in-patients, aged above 65.**
- **Describing the distribution of the diseases according to demographic characteristics, medical departments and causes of admission.**
- **Differentiating between already diagnosed and yet undiscovered cognitive disorders.**
- **Creating an inventory of measures and services that are provided by the hospitals for the (special) care of patients with dementia and delirium.**
- **Identifying approaches to improve care of people with dementia or delirium in the hospital.**
- **Detecting specific care needs and difficulties.**
- **Describing complications, special measures and precautions that were necessary during treatment.**

In a representative study (N=1200) data of in-patients, aged above 65, from 32 randomly selected general hospitals in Bavaria and Baden-Württemberg, are collected. The data collection subdivides into: (1) A survey and cognitive performance testing of patients to determine their cognitive status, (2) a documentation of diagnoses, medication and special treatment arrangements, (3) a survey administered to the nursing staff investigating the effort needed for caring and unique care demands and (4) a data collection at the department level considering special measures and precautions when dealing with cognitively impaired patients.

Organizational Data

- **DRKS-ID: DRKS00006028**
- **Date of Registration in DRKS: 2014/05/15**
- **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.: 66/14 , Ethik-Kommission der Fakultät für Medizin der Technischen Universität München**



Secondary IDs

Health condition or Problem studied

- ICD10: **F00 - Dementia in Alzheimer disease**
- ICD10: **F01 - Vascular dementia**
- ICD10: **F02 - Dementia in other diseases classified elsewhere**
- ICD10: **F03 - Unspecified dementia**
- ICD10: **F05 - Delirium, not induced by alcohol and other psychoactive substances**
- ICD10: **G30 - Alzheimer disease**
- ICD10: **G31 - Other degenerative diseases of nervous system, not elsewhere classified**

Interventions/Observational Groups

- Arm 1: **The data collection subdivides into the following four parts: (1) A survey and cognitive performance testing of patients to determine their cognitive status, (2) a documentation of diagnoses, medication and special treatment arrangements, (3) a survey administered to the nursing staff investigating the effort needed for caring and unique care demands and (4) a data collection at the department level considering special measures and precautions when dealing with cognitively impaired patients.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Epidemiological study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Diagnostic**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Primary endpoint are dementia and delirium at baseline. The cognitive status will be determined using a cognitive test battery. Diagnosis of dementia according to the criteria of DSM-IV, diagnosis of delirium according to the criteria of the CAM.

Secondary Outcome

Determination of special care needs by interviews with care personnel at baseline

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- Medical Center **Bayern und Baden-Württemberg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/06/16**
- Target Sample Size: **1200**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **65 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

In-Patient treatment in a general hospital

Exclusion criteria

Age below 65. In-patient treatment in the departments of neurology, psychiatry, psychosomatics, and geriatrics

Addresses

■ Primary Sponsor

**Klinikum rechts der Isar der TU München
Ismaninger Str. 22
81675 München
Germany**

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: www.med.tu-muenchen.de

■ Contact for Scientific Queries

**Klinik und Poliklinik für Psychiatrie und Psychotherapie der TU
München, Klinikum rechts der Isar
Mr. Dr. Horst Bickel
Ismaninger Str. 22
81675 München
Germany**

Telephone: **+49-89-41404246**

Fax: [---]*

E-mail: [h.bickel at lrz.tum.de](mailto:h.bickel@lrz.tum.de)

URL: [---]*

■ Contact for Public Queries

**Hochschule Mannheim
Ms. Ingrid Hendlmeier
Paul-Wittsack-Str. 10
68163 Mannheim
Germany**

Telephone: **+49-621-292-6079**

Fax: [---]*

E-mail: [i.hendlmeier at hs-mannheim.de](mailto:i.hendlmeier@hs-mannheim.de)

URL: [---]*

■ Collaborator, Other Address

**Fakultät für Sozialwesen, Hochschule Mannheim
Ms. Prof. Dr. Martina Schäufele
Paul-Wittsack-Str. 10
68163 Mannheim
Germany**

Telephone: **+49-621-2926082**

Fax: [---]*



Collaborator, Other Address

Fakultät für Sozialwesen, Hochschule Mannheim

Ms. Prof. Dr. Martina Schäufele

Paul-Wittsack-Str. 10

68163 Mannheim

Germany

Telephone: **+49-621-2926082**

Fax: [---]*

E-mail: **m.schaeufele at hs-mannheim.de**

URL: [---]*

Sources of Monetary or Material Support

■ **Private sponsorship (foundations, study societies, etc.)**

Robert Bosch Stiftung

70005 Stuttgart

Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: **bosch-stiftung.de**

■ **Private sponsorship (foundations, study societies, etc.)**

Deutsche Alzheimer Gesellschaft

10969 Berlin

Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

Status

■ Recruitment Status: **Recruiting complete, follow-up complete**

■ Study Closing (LPLV): **2015/06/30**

Trial Publications, Results and other documents

■ Paper **Bickel H, Hendlmeier I, Heßler JB, Junge MN, Leonhardt-Achilles S, Weber J, Schäufele M: The prevalence of dementia and cognitive impairment in hospitals - results from the General Hospital Study (GHoSt). Dtsch Arztebl Int 2018; 115:**

733-40. DOI: 10.3238/arztebl.2018.0733

- Paper **Hendlmeier I, Bickel H, Hessler JB, Weber J, Junge MN, Schäufele M: Demenzsensible Versorgungsangebote im Allgemeinkrankenhaus. Repräsentative Ergebnisse aus der General Hospital Study (GHoSt). Z gerontol geriat 2018; 51: 509-516. DOI: 10.1007/s00391-017-1339-7**
- Paper **Hessler JB, Schäufele M, Hendlmeier I, Junge MN, Leonhardt S, Weber J, Bickel H. Behavioural and psychological symptoms in general hospital patients with dementia, distress for nursing staff and complications in care: results of the General Hospital Study. Epidemiology and Psychiatric Sciences 2017; 27: 278-287. DOI: 10.1017/S2045796016001098**
- Paper **Hessler JB, Schäufele M, Hendlmeier I, Junge MN, Leonhardt S, Weber J, Bickel H. The 6-Item Cognitive Impairment Test as a bedside screening for dementia in general hospital patients: results of the General Hospital Study (GHoSt). Int J Geriatr Psychiatry 2017; 32: 726-733. DOI: 10.1002/gps.4514**

* 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.