

## Trial Description

### Title

**Translation, cross-cultural Adaptation and Validation of the Family Confusion Assessment Method into German for the Detection of Delirium in Critically Ill Patients**

### Trial Acronym

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### URL of the trial

[---]\*

### Brief Summary in Lay Language

**Delirium is a common complication of critically ill patients. It is a neuropsychiatric syndrome characterized by acute onset, a fluctuating course, an altered level of consciousness, disturbances in orientation, memory, attention, thinking, perception and behavior. Delirium, not induced by alcohol and other psychoactive substances, is the most common complication in the intensive care unit. The incidence of delirium in the ICU ranges from 30 to 87 percent. The most important steps in delirium management are early identification and treatment. Delirium is not always easy to detect or recognize. Family members are often the first to notice subtle changes and the symptoms of delirium.**

**The FAM-CAM is a screening tool for delirium utilizing the observations of family caregivers. The Family-CAM (FAM-CAM) was originally developed by Inouye, M.D. et al. in 1988, based on the CAM. The assessment includes 11 questions directed to a family member.**

**Until now, there is no instrument in German-speaking countries for the detection of delirium by family members.**

**Against this background the aim of this study is to translate the Family Confusion Assessment Method into German and to validate the translated version.**

### Brief Summary in Scientific Language

**Delirium, not induced by alcohol and other psychoactive substances, is the most common complication in the intensive care unit. The incidence of delirium in the ICU ranges from 30 to 87 percent. Delirium is classified into three psychomotor subtypes: hypoactive, hyperactive, and mixed.**

**The most important steps in delirium management are early identification and treatment. There are numerous screening tools validated for the assessment of delirium by clinically trained staff. Delirium is not always easy to detect or recognize. Family members are often the first to notice subtle changes and the symptoms of delirium.**

**The FAM-CAM is a screening tool for delirium utilizing the observations of family caregivers. The Family-CAM (FAM-CAM) was originally developed by Inouye, M.D. et al. in 1988, based on the CAM. The assessment includes 11 questions directed to a family member. The FAM-CAM is intended only to assist with screening and is not intended to provide a clinical diagnosis. Originally validated by Steis, Ph.D. et**

**al the FAM-CAM showed a high sensitivity (88 percent) and specificity (98 percent) and interrater-reliability of 0,85.**

**Until now, there is no instrument in German-speaking countries for the detection of delirium by family members.**

**Against this background the aim of this study is to translate the Family Confusion Assessment Method into German and to validate the translated version.**

**The translation process will be performed according to Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes of the International Society for Pharmacoeconomics and Outcome Research.**

**For testing, the concurrent validity will be compared the German Family Confusion Assessment Method with the reference standard, the Confusion Assessment Method for Intensive Care Unit.**

**IBM SPSS 25 will be used for statistical methods.**

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

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**Description IPD sharing plan**

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## Organizational Data

- DRKS-ID: **DRKS00016930**
- Date of Registration in DRKS: **2019/03/15**
- 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.: **19-1350-101 , Ethikkommission an der Universität Regensburg**

## Secondary IDs

- Universal Trial Number (UTN): **U1111-1228-7879**

## Health condition or Problem studied

- ICD10: **F05 - Delirium, not induced by alcohol and other psychoactive substances**

## Interventions/Observational Groups

- Arm 1: **Verification of concurrent validity is performed in the intensive care unit. Subjects (Test persons) are recruited on the basis of defined inclusion**

**and exclusion criteria.**

**For testing the concurrent validity the Family Confusion Assessment Method is assessed in comparison to the Confusion Assessment Method for Intensive Care Unit for all included critically ill patients.**

**The relatives are informed and sign the consent form for their participation in the study.**

**The consent of critically ill patients is based on a gradual approach:**

**1. Information and consent of the patient, 2. If the patient is not able to consent, but a precautionary authorized or legal representative exists, he / she will be asked to give his / her consent.**

## Characteristics

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

## Primary Outcome

**The primary endpoint is the Cohen's Kappa coefficient comparing the Family Confusion Assessment Method and the Confusion Assessment Method for Intensive Care Unit.**

## Secondary Outcome

**Secondary Outcomes are the Sensitivity and Specificity and the Negative (NPV) and Positive Predictive Value (PPV) of the Family Confusion Assessment Method in critically ill patients to detect Delirium.**

## Countries of recruitment

- **DE Germany**

## Locations of Recruitment

- University Medical Center **Klinik und Poliklinik für Innere Medizin I, Regensburg**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/01/23**
- Target Sample Size: **50**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

## Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

## Additional Inclusion Criteria

### Relatives/Family members:

**Relatives of critically ill patients (Lives with the critically ill patient or personal contact to the critically ill patient at least once a month (with regular contacts by phone or other means of communication) and knows the physical and cognitive functioning of the patient)**

**At least one visit to the intensive care unit**

**18 Years and older (Adult, Older Adult)**

**Possibility of communication in German language (minimum of C1 level of Common European Framework of Reference for Languages)**

**Signed consent form**

### Critically ill patients:

**Intensive Care Stay  $\geq$  48 hours**

**Consciousness position: RASS from -3 to +4**

**Possibility of communication in German language (minimum of C1 level of Common European Framework of Reference for Languages)**

## Exclusion criteria

### Exclusion Criteria for critically ill patients:

**Prefinal Patients**

**Acute Intoxication**

## Addresses

### ■ Primary Sponsor

**Universitätsklinikum Regensburg**

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**Franz-Josef-Strauss-Allee 11**

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

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

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## **Status**

■ Recruitment Status: **Recruiting ongoing**

■ Study Closing (LPLV): **[---]\***

## Trial Publications, Results and other documents

- Background literature <style fontName='DejaVu Sans' isBold='true'>Inouye, S. K., Puelle, M. R., Saczynski, J. S. & Steis, M. R. (2011). The family confusion assessment method (FAM-CAM): Instrument and training manual. Boston, MA: Hospital Elder Life Program.</style>
- Background literature <style fontName='DejaVu Sans' isBold='true'>Steis, M. R., Evans, L., Hirschman, K. B., Hanlon, A., Fick, D. M., Flanagan, N. & Inouye, S. K. (2012). Screening for delirium using family caregivers: Convergent validity of the Family Confusion Assessment Method and interviewer-rated Confusion Assessment Method. Journal of the American Geriatrics Society, 60(11), 2121-2126.</style>

\* *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.*