Trial Description

Title

Patient safety, cost-effectiveness and quality of life: reduction of delirium risk and post-operative cognitive dysfunction (POCD) after elective procedures in the elderly

Trial Acronym

PAWEL

URL of the trial

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Brief Summary in Lay Language

Delirium is a complex syndrome of decreased attention and thought disorder that often occurs after surgery, especially in older adults. Delirium is associated with increased risks for illness and death, and increased costs. Teaching staff and caregivers in a hospital can help to prevent delirium and decrease the risk for future cognitive impairment. We test the effects of such a complex training intervention in 1500 patients age 70 or older in five hospitals, each including at least 2 surgical departments, and monitor delirium frequency and cognitive decline after 6 and 12 month, together with other variables of patients' quality of life and healthcare costs before and after the multimodal intervention, which is implemented consecutively in each setting.

Brief Summary in Scientific Language

Elective surgery aims to improve the quality of life of people in a cost-effective way. However, the perioperative phase is often a trigger of delirium, due to the burden of the anaesthesia, the pain, the surgical procedure, the activation of the immune system, and other related factors. Delirium is associated with higher morbidity and mortality, cognitive impairment, development of dementia, and a higher institutionalization rate. The probability of delirium after an operation increases with the age of the patient and with the presence of pre-existing cognitive impairment, and is also dependent on the skills of the doctors and caregivers.
In this study, we investigate whether a transectorial and multimodal intervention for preventing delirium can improve perioperative care of patients older than 70 years subject to an elective surgery intervention by reducing the prevalence of delirium and the postoperative cognitive decline (POCD) within 6 months. Furthermore, we will investigate if the intervention is cost-effective so that the improvement of quality of life does not involve higher costs and the care needs are lower than in the baseline without intervention.
The study takes place at 5 medical centers (with at least 2 surgical departments each) in the south-west of Germany. It follows a stepped wedge design with cluster randomization of the medical centers, and 6 consecutive measurement points: pre-admission, pre- and postoperatively with daily delirium screening up to day 7, 2 and 6 months after surgery, and long-term follow-up after 12 months. The study population consists of 1500 patients older than 70 years going through

elective operations (heart, thorax, vessels, proximal big joints and spinal cord, genitourinary, gastrointestinal and general elective surgery procedures). In addition, in an already ongoing sub-study named PAWEL-R (R for Risk), a delirium risk score will be developed and validated with 1800 patients (DRKS00012797).

Organizational Data

- DRKS-ID: **DRKS00013311**
- Date of Registration in DRKS: **2017/11/23**
- 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.: **517/2017BO1 , Ethik-Kommission an der Medizinischen Fakultät der Eberhard-Karls-Universität und am Universitätsklinikum Tübingen**

Secondary IDs

Health condition or Problem studied

- ICD10: **F05.0 - Delirium not superimposed on dementia, so described**
- ICD10: **F05.1 - Delirium superimposed on dementia**

Interventions/Observational Groups

- Arm 1: **The intervention implements a trans-sectoral multimodal delirium prevention and management approach, consisting of the following actions, applied to the individual centers after randomization to intervention:**
  • Non-pharmacological preventive interventions will be implemented pre-admission, among them, informative talks, written recommendations, and instructive contacts with the referring doctors regarding the age appropriate medication and interventions to optimize patients' presurgical medical treatment and physical status.
  • Within 4 to 6 weeks before the intervention, nurses and all therapeutic and medical as well as support staff involved in the care of study patients will be trained using a standardized teaching plan on dementia and delirium care, delirium diagnosis and depression at three levels: more than 70% of the staff receive basic training (90 minutes teaching time); more than 20% of nurses receive advanced training ("delirium scout" training – 450 minutes teaching time); and more than 10% receive expert level training ("delirium champion" training –900 minutes teaching time). Additionally, 70% of physicians receive an extra 90 minutes of training on delirium prevention, diagnosis and treatment. The courses will be adjusted to the specific surgical and anaesthesiological departments in order to ensure comparable levels of knowledge between different study sites.

• The decline in sensory function in elderly people often leads to additional psychosocial stressors exacerbated by cognitive impairment. The needs of these patients will be taken into account by interventions aimed at altering the hospital environment. Key interventions are:
o Placing appropriate posters and signage on the wards, patients' rooms and restroom. Tools for temporal and situational orientation, e.g. whiteboards with personal information, date, season and year as well as analogue clocks which can be seen from the bed.
o Providing appropriate tools to prevent falls, e.g. anti-sliding socks, hip protectors.
o Providing special boxes for glasses, hearing aids, and dentures at the reach of the patient at all times.
• Participants at the respective centers will be subject to a manualized peri- and post-operative multimodal delirium prevention and care management, modified according to best practice models such as HELP or "The old patient in the surgery room" (Gurlit and Mollmann, 2008), 12 hours per day 8 a.m. to 8 p.m. on 7 days per week. For this purpose, diagnostic and surgical follow-up examinations will be carried out by trained nurses, nursing assistants or voluntaries.
• Trained psychogeriatric specialists will facilitate the implementation of treatment standards as advised for in the guidelines for perioperative management in patients with delirium (premedication, adaptation of surgery and anaesthesia, pain monitoring, pain treatment appropriate for their age, avoidance of movement restrictions as catheters or infusions, and avoidance of benzodiazepines). At the same time, trained psychogeriatric specialists will implement and supervise individualized daily activities for preventing delirium defined in 6 manualized modules (orientation, activation, mobilization, meal companionship, non-pharmacological anxiety reduction and sleep promotion, pain management) that are carried out by geriatric assistants in nursing (AIN) and trained volunteers (Voluntary Social Year candidates, Federal Social Year candidates (BUFDIs), and students).
•Patients and their family members will be informed verbally about delirium risk and prevention and will receive information materials (leaflets, posters). Family members will provide individual information on the patient, and will be advised to support individualized delirium prevention activities.
•There are 6 consecutive measurement points: pre-admission, pre- and postoperative including daily delirium screening for 7 days after surgery, and 2 and 6 months after surgery, and long-term follow-up after 12 months.

- Arm 2: **Control group receives treatment as usual (TAU).**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **assessor**
- Control: **Active control (effective treament of control group)**
- Purpose: **Prevention**
- Assignment: **Other**
- Phase: **N/A**

Study Type: **Interventional**

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Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **assessor**

Control: **Active control (effective treament of control group)**

Purpose: **Prevention**

Assignment: **Other**

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Delirium prevalence, measured by daily delirium-screening (I-Confusion Assessment Method (I-CAM-S)) over 7 days surgery, as well as after 2 and 6 months, Nursing Delirium Screening Scale (NuDESC) on days 2 and 6 post surgery, and the clinical evaluation.

Secondary Outcome

Delirium Duration as described in the prirmary Outcome assessment. Prevalence of POCD 2 and 6 months after surgery as measured by a neuropsychological test battery (Montreal Cognitive Assessment (MoCA), Trail Making Test A and B (TMT A and B) and digit span backwards) as well as cognitive performance measured with the continuous non-standardized test values of these scales. A cognitive deficit is defined as the presence of a test value <= 0.5 standard deviations, normalized for age, gender and education, in one of these test procedures. Persistance of POCD after 12 months.

For baseline assessment: sociodemographic assessment, subjective memory impairment (SMI), anamnesis (incl. extended Charlson Comorbidity Index (CCI), the American Society of Anesthesiologists Physical Status classification (ASA), CHA2DS2-score, blood markers, delirium history), grip strength, Whisper and visual acuity test, Timed up and go (TUG), Patient Health Questionnaire 4 items (PHQ-4), EuroQol five dimensions questionnaire (EQ-5D-5L), 12-Item Short Form Survey (SF-12), Mini Nutritional Assessment Short Form (MNA-SF), Barthel Index, CSHA Clinical Frailty Scale, the Visual Analogue Scale (VAS), Pittsburgh Sleep Quality Index PSQI (Basic), STOP-BANG, Sniffin' sticks 12, Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE), German Zarit Burden Interview (G-ZBI), medication with anticholinergic drugs.

For planned analyses: Patient Health Questionnaire 4 items (PHQ-4), EuroQol five dimensions questionnaire (EQ-5D-5L), 12-Item Short Form Survey (SF-12), Mini Nutritional Assessment Short Form (MNA-SF), Barthel Index, CSHA Clinical Frailty Scale, amount and duration of restraints, Nurses' observation scale for geriatric patients (NOSGER II), Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE), German Zarit Burden Interview (G-ZBI).

For planned health-economic analyses: For two centers, hospital costs. For patients insured by AOK Baden-Württemberg: service costs of the stay, duration of the stay, and pre and post-hospital costs for 2 years including rehabilitation and health insurance costs of outpatient and inpatient care.

For planned validity assessments of post-operative delirium: I-CAM-S, NuDESC vs. RASS.

For analyses of delirium severity: additional measures of duration and extent of restraints and permanent watch assistants.

For process analyses: knowledge evaluation before/after training, degree of implementation of the intervention. Qualitative assessment: focus group transcripts (n = 10).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Universitätsklinikum, Tübingen**
- Medical Center **Städtisches Klinikum, Stuttgart**
- University Medical Center **Universitätsklinikum , Ulm**
- University Medical Center **Universitätsklinikum , Freiburg im Breisgau**
- Medical Center **HELIOS Klinik, Karlsruhe**
- Medical Center **ViDia Kliniken, Karlsruhe**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/11/20**
- Target Sample Size: **1500**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **70 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Elective surgery (heart, thorax, vessels, proximal big joints and spinal cord, genitourinary, gastrointestinal and general elective surgery procedures) with at least 60 minutes duration of surgery (cut-to-suture-time).

Exclusion criteria

Emergency surgery, newly discovered severe dementia (Red flag: Mini Mental Status Test (MMST) < 15, Montreal Cognitive Assessment (MoCA) < 8) without authorization or legal guardian, 120 km of driving distance to the center, inability to consent due to decreased German language abilities, poor clinical prognosis (survival of less the 15 months).

Addresses

- **Primary Sponsor**

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■ **Collaborator, Other Address**

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Sources of Monetary or Material Support

■ **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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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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Status

- Recruitment Status: **Enrolling by invitation**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** 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.*