Trial Description

Title

Improve Hip Fracture Outcome In The Elderly Patient (iHOPE): a multicentre randomized controlled trial to test the efficacy of spinal versus general anaesthesia

Trial Acronym

iHOPE

URL of the trial

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Brief Summary in Lay Language

iHOPE aims to evaluate the effect of two different standard anaesthesia care approaches (spinal and general anaesthesia) for hip fracture surgery on the outcomes of patients up to 365 ± 60 days. iHOPE aims to optimize the efficacy, clinical and cost effectiveness of anaesthesia care for hip fracture patients.

Brief Summary in Scientific Language

This is a pragmatic, confirmatory, comparative, national, multicentre, actively controlled, randomized, open-label, prospective, parallel-group study that will enroll 1032 patients with hip fracture (femoral neck or intertrochanteric fracture) needing surgical treatment.
The aim of this study is to optimize patient care. For this purpose, spinal and general anesthesia with regard to recovery and mental (postoperative delirium, depression and satisfaction with treatment) and physical (mortality, regaining running and self-reliance, severe new comorbidities) health status of elderly patients after their hip replacement surgery will be compared.

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

[---]*

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00013644**
- Date of Registration in DRKS: **2018/04/10**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***

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- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **EK 022/18 , Ethik-Kommission an der Medizinischen Fakultät der RWTH Aachen**

Secondary IDs

Health condition or Problem studied

- ICD10: **S70-S79 - Injuries to the hip and thigh**

Interventions/Observational Groups

- Arm 1: **Hip fracture surgery with standard care general anaesthesia**
- Arm 2: **Hip fracture surgery with standard care spinal anaesthesia**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

To test Efficacy of spinal versus general anaesthesia on allcause mortality and new-onset (i.e. not pre-existing at time of surgery) serious cardiac and pulmonary complications up to 30-days after hip fracture surgery.

Secondary Outcome

1) Difference in the proportion of patients alive and delirium free in the first 4 days after hip fracture surgery. Delirium will be assessed via in-person interview by the validated, high sensitive and specific assessment tool 3D-Confusion Assessment Method (3D-CAM). It will be applied at baseline and daily on the first 4 postoperative days.
2) Difference in the proportion of patients with postoperative pain; and in the characteristics and duration of postoperative pain between the two treatment arms. Pain will be assessed via numeric rating scale (NRS 0-10) and questions derived from the Brief Pain Inventory and the German pain questionnaire. Assessment will be performed via in-person interview at baseline and each postoperative visit during hospital stay. After discharge, it will be performed via telephone interview at each follow-up visit.
3) Difference in the satisfaction with care between the two treatment arms, assessed at day 4 or the day of discharge (whichever occurs first). The Bauer Patient Satisfaction Questionnaire will be used via in-person interview on postoperative day 4 or at discharge (whichever occurs first), to assess the patients´ satisfaction.
4) Difference in the number of in-hospital events, which include (but not limited to): Planned and unplanned admission to critical care; length of hospital and intensive care stay; length of hospital stay longer than expected; independence in walking and the need for assistive devices for walking at hospital discharge; postoperative hospital discharge destination; in hospital all-cause mortality and severe new-onset complications as those used by the NSQIP. These events will be assessed on the discharge day from hospital or at least at postoperative day 30 via in-person interview and medical record review.
5) Difference in the proportion or means of long-term outcomes at day 30 ± 3, day 180 ± 45 and day 365 ± 60 after randomization will include: All cause-mortality, independence in walking and need for assistive devices for walking; chronic pain; ability to return home; cognitive function via Short blessed test (SBT); and overall health and disability via World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0). Except of the cognitive function and chronic pain, which could only be assessed via telephone interview of the patient, all other data could also be assessed via telephone interview of the proxy.
6) Difference in the proportion of patients with perioperative serious adverse events like intraoperative cardiac arrest; malignant hyperthermia; intraoperative anaphylaxis; intraoperative aspiration; total spinal anaesthesia; epidural hematoma; paralysis of the lower extremities lasting greater than 24 hours following spinal anaesthesia; fall within 12 hours of anaesthesia care. These data will be assessed during the surgery and the postoperative in-hospital visits via in-person interview and medical record review.
7) Sensitivity and subgroup analyses of the primary outcome will consider the baseline proportion of patients with depression and frailty. Depression will be assessed via the 15-items short version of the Geriatric Depression Scale (GDS) at baseline via in-person interview. Frailty assessment will be performed according to phenotype-model of Fried at baseline via in-person interview. Four of originally five Fried-criteria will be assessed: fatigue, maximal grip strength assessment of the dominant hand, physical activity (employing the Minnesota Leisure Time Activities Questionnaire) and weight loss in the past year. Gait velocity as the fifth Fried criterion will be omitted in this study for obvious reasons.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Anästhesiologie, Aachen**
- University Medical Center **Klinik für Anästhesiologie mit Schwerpunkt operative Intensivmedizin, Berlin**
- University Medical Center **Klinik für Anästhesiologie und Operative Intensivmedizin, Bonn**
- University Medical Center **Klinik für Anästhesiologie, Düsseldorf**
- University Medical Center **Kilinik für Anästhesiologie, Intensivmedizin und Schmerztherapie, Frankfurt a.M.**
- University Medical Center **Kilinik für Anästhesiologie, Hamburg**
- University Medical Center **Klinik für Anästhesiologie und Intensivmedizin, Hannover**
- University Medical Center **Klinik für Anästhesiologie, Mainz**
- University Medical Center **Klinik für Anästhesiologie, München**
- University Medical Center **Klinik für Anästhesiologie, operative Intensivmedizin und Schmerztherapie, Münster**
- Medical Center **Klinikum am Steinenberg, Klinik für Anästhesiologie, operative Intensivmedizin, Notfallmedizin, Schmerztherapie und Palliativmedizin, Reutlingen**
- Medical Center **Klinikum, Klinik für Anästhesiologie und operative Intensivmedizin, Köln Merheim**
- University Medical Center **Klinik für Anästhesiologie, Würzburg**
- Medical Center **Petrus Krankenhaus, Klinik für Anästhesie, Intensiv- und Schmerztherapie, Wuppertal**
- Medical Center **Gemeinschaftskrankenhaus, Fachabteilung Anäthesie, Intensiv- und Schmerzmedizin, Bonn**
- University Medical Center **Klinik für Anäthesiologie, operative Intensivmedizin und Schmerzmedizin, Stuttgart**
- Medical Center **Westpfalz-Klinikum GmbH, Klinik für Anästhesie, Intensiv-, Notfallmedizin und Schmerztherapie 1, Kaiserslautern**
- Medical Center **Krankenhaus der Barmherzigen Brüder, Fachabteilung für Anästhesie und Intensivmedizin, Trier**
- Medical Center **St.-Antonius-Hospital, Klinik für Anästhesie und Operative Intensivmedizin, Eschweiler**
- Medical Center **St. Augustinus Krankenhaus, Klinik für Anästhesie, Intensivmedizin und Schmerztherapie , Düren**
- Medical Center **Jüdisches Krankenhaus, Klinik für Anästhesiologie und Schmerztherapie, Berlin**

- Medical Center **Klinikum Nord, Klinik für Anästhesiologie, operative Intensivmedizin und postoperative Intensivmedizin, Dortmund**
- Medical Center **Maria Hilf Kliniken, Klinik für Anästhsiologie und operative Intensivmedizin , Mönchengladbach**
- Medical Center **Städtisches Klinikum, Klinik für Anästhesie, operative Intensiv- und Palliativmedizin, Solingen**
- Medical Center **Klinikum Vest, Zentrum für Anästhesiologie, Intensivmedizin und Schmerztherapie, Recklinghausen**
- Medical Center **Carl-Thiem-Klinikum, Klinik für Anästhesiologie, Intensivtherapie und Palliativmedizin, Cottbus**
- Medical Center **DIAKOVERE Krankenhaus, Klinik für Anästhesiologie, Intensiv-, Notfall- und Schmerzmedizin , Hannover**
- Medical Center **Unfallkrankenhaus, Klinik für Anästhesiologie, Intensiv- und Schmerztherapie, Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/04/25**
- Target Sample Size: **1032**
- 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

Age ≥ 65 years; signed informed consent; suffers from intra-/extracapsular hip fracture (e.g. femoral neck fracture, subtrochanteric or intertrochanteric fracture), planned surgical treatment via hemiarthroplasty, total hip arthroplasty or appropriate osteosynthetic procedure

Exclusion criteria

People who are institutionalized by court or administrative order; planned concurrent surgery not amenable to spinal anaesthesia; absolute contraindications to spinal anaesthesia; periprosthetic fracture; prior participation in the iHOPE study; as determined by the attending surgeon, the attending anaesthesiologist, or the site principle investigator or their designate, that the patient or the attending team would not be suitable for a randomization procedure

Addresses

■ **Primary Sponsor**

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■ **Contact for Scientific Queries**

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■ **Contact for Public Queries**

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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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Status

- Recruitment Status: **Recruiting ongoing**
- 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.*