



Trial Description

Title

Prospective evaluation of screen-based interventions with a standalone system

Trial Acronym

Orbeye study

URL of the trial

[---]*

Brief Summary in Lay Language

The current evolution of exoscopic surgery marks a paradigm shift in neurosurgery and comes with multiple new systems ready for market introduction. Hence, it is vital to analyze the impact of the technology on neurosurgical practice. Multiprofessional scientific effort is needed to accompany the intraoperative application and further development of the systems.

Brief Summary in Scientific Language

Coming with a broad range of novel digital visualization options, videoscopes are a promising alternative to established surgical microscopes. Standalone exoscopes, in particular, offer different advantages and disadvantages in surgical routine than hybrid technologies. This study examines the utilization and image quality of the Olympus Orbeye in neurosurgical routine interventions in head and spine. The goal is to define the most eligible procedures and intraoperative setups as well as to analyze the image quality in detail. Thereby, the study will contribute to more general insights into requirements of neurosurgical visualization. Patients with cranial and spinal pathologies will be selected by the surgeon for screen-based interventions. A switch to conventional ocular-based surgery is possible at any time.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00017112**
- Date of Registration in DRKS: **2019/05/02**



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- 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.: **EA1/048/19** , **Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- ICD10: **C71 - Malignant neoplasm of brain**
- ICD10: **M51 - Other intervertebral disc disorders**

Interventions/Observational Groups

- Arm 1: **Surgery with videoscope**
- Arm 2: **Surgery with conventional surgical microscope**
- Arm 3: **Surgery with hybrid exoscope**

Characteristics

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



Primary Outcome

- **definition of most relevant application areas (type of intervention, duration of surgery, surgical access, number of surgeon users per intervention, additional equipment, intraoperative setup) of the videoscope in neurosurgery - documentation and user survey during and after each surgery**

Secondary Outcome

- **analysis of image quality in relation to the surgical intervention**
- **definition of best practice-scenarios**

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- University Medical Center **Charité-Universitätsmedizin Berlin, Berlin**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2019/05/08**
- Target Sample Size: **30**
- 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

- **Cranial or spinal pathologies suitable for microsurgery**
- **age > 18 years**
- **cases suitable for both microscope and exoscope/videoscope**
- **surgeons trained in both modalities**

Exclusion criteria

Multimorbidity

Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

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

Charité Campus Charité Mitte
Charitéplatz 1



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

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Status

- Recruitment Status: **Recruiting planned**
- 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.