PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

The spinal anesthesia with hyperbaric Lokalanästhestikum performed in the lateral position, compared to general anesthesia in outpatient anesthesia, in terms of effectiveness, process times, hemodynamic stability, perioperative complications, and postoperative pain

Trial Acronym

ESG-unilaterSPA

URL of the trial

[---]*

Brief Summary in Lay Language

In this study, the method of unilateral spinal anesthesia should be investigated in orthopedic outpatient surgery. The effectiveness of unilateral spinal anesthesia is checked by measuring the resistance of the skin and determines its spread. Are investigated complications of the procedure.

Brief Summary in Scientific Language

This study will examine how the use of spinal anesthesia with hyperbaric lokalanästhetics performed in the lateral position, effect compared to general anesthesia in outpatient anesthesia. Both process times, the efficacy / objectification with the ESG spinal anesthesia, the hemodynamic stability during anesthesia and in the recovery room, as well as possible complications during anesthesia and in the recovery room to be examined. Furthermore, patients are interviewed using a standardized questionnaire postoperatively to your satisfaction, intraoperative and postoperative pain and the use of postoperative analgesics

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00004906**
- Date of Registration in DRKS: **2013/04/30**
- 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.: **29/11/10 , Ethik-Kommission der Medizinischen Fakultät der Georg-August-Universität Göttingen**

Secondary IDs

Health condition or Problem studied

- ICD10: **M23 - Internal derangement of knee**
- ICD10: **M17 - Gonarthrosis [arthrosis of knee]**

Interventions/Observational Groups

- Arm 1: **Anesthetic procedures: spinal anesthesia with hyperbaric bupivacaine 0.5% in lateral position: completely objective, sympathetic unilateral spinal anesthesia for ambulatory surgery on the knee joint monitoring with skin resistance measurement with the ICM (electric sympatho graph)**
- Arm 2: **Anesthetic procedures:General anesthesia with remifentanil and propofol for laryngeal mask airway management outpatient orthopedic surgery on knee**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

1 Process times SPA vs. general an.
- Time to implement the spinal anesthesia /general anesthesia., beginning OP
- Time seam, recovery
- Dismissal time recovery
- Staff retention time recovery
2 Unilateral spinal anesthesia, by testing the sensory / motor blockade
- Objective testing with measurement of sympatic activity by measuring the skin conductance (ESG-Electric sympatho graphy)

Secondary Outcome

perioperative complications - anesthetic protocol
postoperative pain - Questionnaire

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **ZARI, Göttingen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/04/01**
- Target Sample Size: **120**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

Be included in the study 120 male or female patients who undergo elective outpatient arthroscopy of the knee joint. This included 60 patients who received

anesthesia as a unilateral spinal anesthesia and 60 patients receiving general anesthesia

Exclusion criteria

Unsuitability for the anesthetic procedure

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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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

** 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.*