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

Trial Description

Title

Comparison of intravenous regional anesthesia of Biercompared to the axillary plexus anesthesia, infiltration anesthesia and general anesthesia in surgical procedures of the upper extremity in terms of effectiveness, process times, activity of the sympathetic nervous system, perioperative complications and postoperative pain

Trial Acronym

ESG-Hand

URL of the trial

[---]*

Brief Summary in Lay Language

Comparison of different anesthetic techniques at hand surgical procedures, with process times, patient satisfaction and the measurement of sympathetic nerve activity with the ESG.

Brief Summary in Scientific Language

In this study, various established in clinical practice of anesthesia should be investigated in ambulatory surgery of the upper extremity. These are the following general anesthesia, axillary brachial plexus block, IV regional anesthesia and infiltration anesthesia. The anesthesia method are compared in terms of processing time, success rate, hemodynamic stability, complications, activity of the sympathetic nervous system, postoperative pain and satisfaction of patients and surgeons with anesthesia. These patients are interviewed postoperatively using a standardized interview.

Organizational Data

- DRKS-ID: **DRKS00004905**
- 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.: **15/2/11 , Ethik-Kommission der Medizinischen Fakultät der Georg-August-Universität Göttingen**

Secondary IDs

Health condition or Problem studied

- ICD10: **G56.0 - Carpal tunnel syndrome**
- Free text: **Anesthesia for carpal tunnel syndrome**

Interventions/Observational Groups

- Arm 1: **Anesthesia: For outpatient surgery on the hand is for anaesthesie the IV block anesthesia from Bier. It is measured during the procedure the skin resistance of the patient (ESG - Electric sympatho graphy). Be compared alongside the sympathetic tone, process times, hemodynamic stability, incidence of perioperative complications and patient satisfaction.**
- Arm 2: **Anesthesia: For outpatient surgery on the hand is for anaesthesie the local infiltration anaesthesia It is measured during the procedure the skin resistance of the patient (ESG - Electric sympatho graphy). Be compared alongside the sympathetic tone, process times, hemodynamic stability, incidence of perioperative complications and patient satisfaction.**
- Arm 3: **Anesthesia: For outpatient surgery on the hand is for anaesthesie the axillary brachial plexus bloc. It is measured during the procedure the skin resistance of the patient (ESG - Electric sympatho graphy). Be compared alongside the sympathetic tone, process times, hemodynamic stability, incidence of perioperative complications and patient satisfaction.**
- Arm 4: **Anesthesia: For outpatient surgery on the hand is for anaesthesie the general anesthesia. It is measured during the procedure the skin resistance of the patient (ESG - Electric sympatho graphy). Be compared alongside the sympathetic tone, process times, hemodynamic stability, incidence of perioperative complications and patient satisfaction.**

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**

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

- Process time:
Implementing anesthesia to release anesthesia, cut / weld time, OP end up recording the recovery room

- Effectiveness of anesthesia
Sensory / motor testing of the surgical area, measurement of sympathetic blockade on the basis of skin resistance

- Measurement of sympathetic activity (electrical sympatho graphy) intraoperatively by the change in skin resistance

- Questionnaire Postoperatively (after surgical day / 2 days)
Satisfaction school grade, preoperative pain (scale Nummeric rating scale 1-10), intraoperatively, postoperatively, 1day, 2day, regimen analgesics, adjunctive Postoperative nausea and vomiting, pain puncture site

Secondary Outcome

Perioperative complications - anesthetic protocol
Hemodynamic stability - anesthesia protocol

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **ZARI, Göttingen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/07/01**
- Target Sample Size: **160**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **90 Years**

Additional Inclusion Criteria

Be included in the study 160 male and female patients who are undergoing elective outpatient surgery of the upper extremity. In each case, 40 patients will be enrolled, who receive anesthesia than general anesthesia, an axillary brachial plexus block, an IV regional anesthesia or infiltration anesthesia

Exclusion criteria

No suitability for anesthesia

Addresses

- **Primary Sponsor**

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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.*