Trial Description

Title

Comparison ultrasound-guided vs. Nerve-controlled peripheral nerve blocks of the lower extremity in terms of needle-nerve distance, block characteristics and magnetic resonance tomographic and sonographic changes in the nerve

Trial Acronym

DIB-MRT

URL of the trial

[---]*

Brief Summary in Lay Language

In this study, differences between the nerve-controlled (classic standard method: Stimulation via puncture needle triggers motor response as success control off) and the ultrasound-guided (already established standard procedures under direct vision) peripheral nerve blockade in the lower limb, combined with general anesthesia are examined. It should be clarified by ultrasound measurement of how far the needle tip is located to the nerve by stimulator- versus ultrasound-method. Changes in the diameter of the nerve anesthetized to be captured by ultrasound in both methods in order to detect possible influences of the needle position on the nerve swelling.
On the first postoperative day it should be clarified in a magnetic resonance tomographic examination whether the nerve block causes density differences or persistent nerve swelling at the nerve. A comparison of image morphology in patients with surgical intervention without regional anesthesia should clarify whether only the surgical procedure and the associated signal transduction of pain causes nervous changes of image morphology. For these purposes, an image of the native nerve preoperatively should be made and the pre- and postoperative images are compared with each other in connection with all patients. It should be further examined whether the localization process and thus the distance between the needle tip and nerve causing differences in image morphology.
Other parameters are process-times, characteristics of the peripheral nerve block (time to onset, duration and quality), hemodynamic stability during general anesthesia and in the recovery room, as well as potential complications during anesthesia and in the recovery room will be examined.
Finally, patients are interviewed using a standardized questionnaire to your satisfaction and pain in the investment of regional anesthesia and the first and second postoperative day.

Brief Summary in Scientific Language

In this study, differences between the nerve-controlled (classic standard method: Stimulation via puncture needle triggers motor response as success control off) and the ultrasound-guided (already established standard procedures under direct vision) peripheral nerve blockade in the lower limb, combined with general anesthesia are examined.

It should be clarified by ultrasound measurement of how far the needle tip is located to the nerve by stimulator- versus ultrasound-method. Changes in the diameter of the nerve anesthetized to be captured by ultrasound in both methods in order to detect possible influences of the needle position on the nerve swelling. On the first postoperative day it should be clarified in a magnetic resonance tomographic examination whether the nerve block causes density differences or persistent nerve swelling at the nerve. A comparison of image morphology in patients with surgical intervention without regional anesthesia should clarify whether only the surgical procedure and the associated signal transduction of pain causes nervous changes of image morphology. For these purposes, an image of the native nerve preoperatively should be made and the pre- and postoperative images are compared with each other in connection with all patients. It should be further examined whether the localization process and thus the distance between the needle tip and nerve causing differences in image morphology.
Other parameters are process-times, characteristics of the peripheral nerve block (time to onset, duration and quality), hemodynamic stability during general anesthesia and in the recovery room, as well as potential complications during anesthesia and in the recovery room will be examined.
Finally, patients are interviewed using a standardized questionnaire to your satisfaction and pain in the investment of regional anesthesia and the first and second postoperative day.

Organizational Data

- DRKS-ID: **DRKS00008767**
- Date of Registration in DRKS: **2015/06/23**
- 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.: **4/1/12 , Ethik-Kommission der Medizinischen Fakultät der Georg-August-Universität Göttingen**

Secondary IDs

Health condition or Problem studied

- ICD10: **G57 - Mononeuropathies of lower limb**

Interventions/Observational Groups

- Arm 1: **Implementation of peripheral nerve block with nerve stimulator-controlled method> postoperative MRI**
- Arm 2: **Implementation of peripheral nerve block with ultrasound guided method> postoperative MRI**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **assessor, data analyst**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

1) Sonografic distance between needle tip and nerve at a stimulation current of 0.5mA while nerve blockade preoperatively
2) Sonographic measurement of nerve cross-section before and after injection of the local anesthetic at the plant nerve block preoperatively
3) Acquisition MRI-morphological changes (nervous edema, inflammation, density) MRI pre- (12 hours ago) and postoperatively (12 hours later)

Secondary Outcome

1) Patient Satisfaction - Postoperative care unit, 1-6 grade
2) Post-operative pain - Postoperative care unit, Nummeric rating scale (1-10)
3) PONV - Apple Score, Postoperative care unit
4) hemodynamic stability - anesthesia protocol
5) process times - anesthesia protocol

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Anästhesiologie, Göttingen**

Recruitment

-

Planned/Actual: **Actual**

- (Anticipated or Actual) Date of First Enrollment: **2015/10/16**
- Target Sample Size: **35**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **85 Years**

Additional Inclusion Criteria

In the study patients will be included , who undergo electively an intervention of the lower limb-surgery (eg, knee joint and ankle arthroscopy, metal distances, foot surgery), where standard general anesthesia or peripheral nerve block would be carried out by nerve stimulator or ultrasound.
The study included only patients able to consent to participate.
After consent to the study, the patients will be enrolled, which get as anesthetic procedures a combination anesthesia or regional anesthesia with mono-block of the sciatic nerve.

Exclusion criteria

No consent, lack of capacity to consent.
Pre-existing nerve damage, polyneuropathy, infection in the area of any planned nerve blockade, muscle and nerve disease, allergy to local anesthetics, heart failure> NYHA II, severe lung disease, known strong postoperative nausea and vomiting, known or suspected difficult airway management.

Addresses

- **Primary Sponsor**

  Universitätsmedizin Göttingen
  Zentrum Anästhesiologie, Rettungs- und Intensivmedizin
  Mr. Dr. med. Ingo Bergmann
  Robert-Koch Str. 40
  37075 Göttingen
  Germany

  Telephone: **0551-3922995**
  Fax: **[---]***
  E-mail: **ingo.bergmann at med.uni-goettingen.de**
  URL: **[---]***

- **Contact for Scientific Queries**

Contact for Scientific Queries

UMG Göttingen
Mr. Dr. med Ingo Bergmann
Robert-Koch Str. 40
37075 Göttingen
Germany

Telephone: **0551 / 3922995**
Fax: **[---]***
E-mail: **Ingo.Bergmann at med.uni-goettingen.de**
URL: **[---]***

■ **Contact for Public Queries**

UMG Göttingen
Mr. Dr. med Ingo Bergmann
Robert-Koch Str. 40
37075 Göttingen
Germany

Telephone: **0551 / 3922995**
Fax: **[---]***
E-mail: **Ingo.Bergmann at med.uni-goettingen.de**
URL: **[---]***

■ **Collaborator, Other Address**

Abteilung Neuroradiologie, Universitätsmedizin Göttingen
Rober-Koch St. 40
37075 Göttingen
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Sources of Monetary or Material Support

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

UMG Göttingen
Mr. Dr. med Ingo Bergmann
Robert-Koch Str. 40
37075 Göttingen
Germany

Telephone: **0551 / 3922995**
Fax: **[---]***

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

UMG Göttingen
Mr. Dr. med Ingo Bergmann
Robert-Koch Str. 40
37075 Göttingen
Germany

Telephone: **0551 / 3922995**
Fax: **[---]***
E-mail: **Ingo.Bergmann at med.uni-goettingen.de**
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2016/10/16**

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.*