Trial Description

Title

**Postoperative analgesia after total knee arthroplasty:
Intra-articular catheter vs. Continuous femoral nerve block**

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

**One of the standard therapies for postoperative pain treatment after implantation of a total knee arthroplasty for osteoarthritis in the knee joint , has been to insert a so-called continuous femoral nerve-block. This is a pain catheter , which is inserted in the groin in the neurovascular sheath and through continuous delivery of a drug via a pump leads to stopping the pain transmission. This catheter is placed by the anaesthesiologists right before surgery.
Another method , which is increasingly becoming the focus of interest , represents the aplication of a pain catheter directly into the operated knee joint. The orthopedic surgeon inserts it to the knee joint prior to wound closure after surgery. An attached balloon is then continuously aplicating the drug directly into the knee joint.
The two approaches are currently effective pain therapies with few risks for the patient.
We initiated this study to directly compare these methods with each other, trying to figure out which method of pain therapy after implantation of a total knee replacement for our patients is the most effective .
There will be two comparison groups: Group A will recieve therapy by intra-articular catheter, the therapy of Group B will be a femoral nerve catheter . The investigation period covers the first 5 days postoperatively. During this period the pain is documented by visual analog scale and a comparison of mobilization and mobility will be done.**

Brief Summary in Scientific Language

After total knee replacement an effective analgesia postoperatively has enormous significance . The aim of the study is to compare the use of an intra-articular catheter system for pain therapy to the application of a continuous femoral nerve block. In addition it will be examined whether it improves knee mobility and especially a rapid mobilization can be achieved postoperatively.

It is a single-center clinical- experimental study.The type of study is prospective randomized.

The comparison groups :

Group A receives an intra-articular catheter intraoperatively , through which a a mixture of 200 ml ropivacaine (7.5mg/ml) , 150ml NaCl and 20mg morphine is administered (flow rate of 8ml/h)

Group B receives preoperativley a continuous femoral nerve block with constant application of ropivacaine (8ml/h, 2mg/ml)

In addition infiltration is performed intraoperatively in both groups with 20ml Ropivacain (7.5mg/ml) and a 30ml bolus is given through drainage after wound closure.

Follow-up includes first 5 days postoperatively. The primary endpoint is VAS pain on first day. Secondary outcomes include the mobilization, knee flexion , the need for additive opiates as well as the initiation time in the OR, operationtime and length of hospital stay.

Organizational Data

- DRKS-ID: **DRKS00006146**
- Date of Registration in DRKS: **2014/05/23**
- 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.: **FF 6/2014 , Ethikkommission der Landesärztekammer Hessen**

Secondary IDs

Health condition or Problem studied

- Free text: **Pain intensity after toatal knee arthroplasty**
- Free text: **Mobilization / mobility after total knee arthroplasty**
- ICD10: **R52.9 - Pain, unspecified**
- ICD10: **M17.1 - Other primary gonarthrosis**

Interventions/Observational Groups

- Arm 1: **Group A receives an intra-articular catheter intraoperatively , through which a a mixture of 200 ml ropivacaine (7.5mg/ml) , 150ml NaCl and 20mg morphine is administered (flow rate of 8ml/h)**
  (aproximately 44 hours postoperative)

- Arm 2: **Group B receives preoperativley a continuous femoral nerve block with**

constant application of ropivacaine (8ml/h, 2mg/ml)

(aproximately 44 hours postoperative)

Characteristics

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

Primary Outcome

VAS pain postoperative day 1

Secondary Outcome

- Pain intensity on VAS pain (day 2, 3, 4 and 5 after surgery)
- Necessity of additive intake of opiates (daily day 1-5)
- Maximum flexion knee joint (daily day 1-5)
- Mobilization of> 3 feet on crutches (hall mobilization) (daily day 1-5)
- Initiation time (from start of anesthesia preparation to skin incision)
- Duration of inpatient treatment

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Orthopädische Klinik, St. Josefs Hospital , Wiesbaden**

Recruitment

- Planned/Actual: **Actual**
-

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2014/05/26**

- Target Sample Size: **120**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **50 Years**
- Maximum Age: **85 Years**

Additional Inclusion Criteria

- both sexes
- Age between 50 and 85 years
- Able to consent or legally competent patient
- Arthritis of knee, possibly post-traumatic
- Provided an indication for implantation of total knee replacement
- No known allergy to ropivacaine or other local anesthetics
- No contraindication for NFK (tumors, infections in the puncture area, neurological disorder characterized by nerve damage, femoral vascular bypass)
- Consent for participation in the study with appropriate signing of the declaration of consent.

Exclusion criteria

- ASA IV
- Anticoagulation with Plavix or therapeutic administration of low-molecular-weight heparins
- Chronic pain patients with pre-existing long-term opiate consumption

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 complete, follow-up complete**
- Study Closing (LPLV): **2014/11/21**

Trial Publications, Results and other documents

- Paper **[---]***

** 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.*