Trial Description

Title

The effect of extra-epineural administered dexmedetomidine: a volunteer study

Trial Acronym

Dexmedetomidine volunteers study

URL of the trial

[---]*

Brief Summary in Lay Language

A block of a nerv of the hand (ulnar nerve) with Naropin 0,75% (= a localanaesthetiv) causes motoric and sensoric block with a duration of 6 to 10 hours. For a complete ulnar nerve block a volume of 3ml local anaesthetic is needed.
Special drugs (Alpha-2-adrenoceptor agonists) have been shown to prolong duration of peripheral nerve blocks. Dexmedetomidine is a new medication for sedation in intensive care medicine. It is a selective alpha-2-adrenoceptor agonist like clonidine.
We would like to prove this effect in a volunteers´study. The volunteers are parted into 3 groups:
Group 1: volunteers are received an ultrasound guided nerve block with 22.5mg Ropivacain and 0.2ml sodium and 5ml sodium intravenously as a placebo.
Group 2: volunteers are received an ultrasound guided nerve block with 22.5mg Ropivacain and 20µg Dexdor and 5ml sodium intravenously as a placebo
Group 3: volunteers are received an ultrasound guided nerve block with 22.5mg Ropivacain and 0.2ml sodium and 20µg Dexdor (0.2ml) with 4.8ml sodium intravenously.
Before the block and 2,4,6,8,10,15,20,30 and 60 minutes after the block, then every 30 min sensory block is tested by pinpricks at 5 defined locations in the hand. Motor block is tested by thumb adduction.
Aim of the study is to proove the prolongation of block duration after application of dexdor.
In addation we would like to test the way of action- if the possible positive effect works locally or systemic.
The get the maximum profite we designed a volunteers study.

Brief Summary in Scientific Language

Possible prolongation of block duration after application of dexdor. We designed a volunteers´ study. The way of action should be claryfied: if the effect is systemic or local.

Organizational Data

- DRKS-ID: **DRKS00003529**

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- Date of Registration in DRKS: **2012/03/29**
- 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.: **5/2012 , Ethikkommission der Medizinischen Universität Wien**

Secondary IDs

- EudraCT-No.
(for studies acc. to Drug Law): **2012-000030-19**

Health condition or Problem studied

- Free text: **healthy volunteers**

Interventions/Observational Groups

- Arm 1: **12 volunteers are received an ultrasound guided nerve block with 22.5mg Ropivacain and 0.2ml sodium and 5ml sodium intravenously as a**
- Arm 2: **12 volunteers are received an ultrasound guided nerve block with 22.5mg Ropivacain and 20µg Dexdor and 5ml sodium intravenously as a**
- Arm 3: **12 volunteers are received an ultrasound guided nerve block with 22.5mg Ropivacain and 0.2ml sodium and 20µg Dexdor(0.2ml) with 4.8ml sodium intravenously.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist**
- Control: **Placebo**
- Purpose: **Pharmacogenetics**
- Assignment: **Parallel**
- Phase: **I**
-

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Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **Yes**

Primary Outcome

Investigation of the prolongation of sensory and motor blockade of the ulnar nerve by dexmedetomidine added to ropivacaine.
Sensory and motor block will be evaluated as follows:
Prior the block, 2 min, 4 min, 6 min, 8 min, 10 min, 15 min, 20 min, 30 min, 60 min, after the block and then every 30 min until complete recovery.
Evaluation of sensory scores:
A pinprick test in comparison with the contralateral area propria of the ulnar nerve will be performed (0% = no difference to the contra lateral side; 100% = complete sensory loss).
Evaluation of motor scores:
-3 = no difference, adduction against contra-force possible

Secondary Outcome

The secondary outcome parameter is the site of action (systemic versus local).
Test timepoints are the same because it is a blind study.

Countries of recruitment

- AT **Austria**

Locations of Recruitment

- University Medical Center **Medizinsiche Universität Wien, Universitätsklinik für Klinische Pharmakologie, Wien**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/04/02**
- Target Sample Size: **36**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **18 Years**
- Maximum Age: **45 Years**

Additional Inclusion Criteria

- Healthy male volunteers aged between 18 and 45 years
- BMI < 30 kg/m2
- Written informed consent given by volunteers after being provided with detailed information about the nature, risks, and scope of the clinical study as well as the expected desirable and adverse effects of the drug
- No legal incapacity and/or other circumstances rendering the volunteer unable to understand the nature, scope and possible consequences of the study

Exclusion criteria

Anatomical abnormalities of the forearm identified by physical examination, use of NSAID during the last 2 weeks, known allergy or hypersensitivity against ropivacaine or other amino-amide local anaesthetics and dexmedetomidine, participation in another clinical study within the last 4 weeks prior to study, coagulopathy, abnormalities in ECG that are considered clinically relevant like AV-block or bradycardia, hypotony, unreliability and/or lack of cooperation and mobility, other objections to participate in the study in the opinion of the investigator

Addresses

- **Primary Sponsor**

  Medizinische Universität Wien, Universitätsklinik für Klinische Pharmakologie
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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): **2012/05/15**

Trial Publications, Results and other documents

- Paper **Astract in www.pubmed.gov**

** 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.*