# Evaluation of mepivacaine ED95 for peripheral nerve blocks using ultrasound guidance

Submission date	Recruitment status No longer recruiting	Prospectively registered		
19/09/2007		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
27/09/2007		[X] Results		
Last Edited	Condition category	[] Individual participant data		
06/08/2021	Signs and Symptoms			

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

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#### Contact details

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#### Additional identifiers

Protocol serial number N/A

## Study information

#### Scientific Title

Evaluation of mepivacaine ED95 for peripheral nerve blocks using ultrasound guidance

#### Study objectives

To determine the 50% Effective Dose (ED50) and 95% Effective Dose (ED95) volume of 1% mepivacaine relative to the cross-sectional area of the ulnar nerve using ultrasound guidance for performance of an adequate sensory nerve block.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics approval received from the local ethics committee (Kantonale Ethikkommission Bern [KEK]) on the 6th June 2006 (ref: 76/06).

#### Study design

Up-and-down method study, patient is their own control. Volunteers and physician performing the block are blinded to the volume injected.

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Peripheral regional anaesthesia

#### **Interventions**

The ulnar nerve of the non-dominant forearm of the volunteer is scanned and its outer limit is tracked to calculate the cross-sectional area of the nerve. A short bevel facet tip ultrasound needle is advanced under direct ultrasonographic visualisation next to the nerve and the local anaesthetic is applied around the nerve.

The volume of local anaesthetic solution is calculated dependent on the measured cross-sectional area of the nerve, starting with 0.4 ml/mm^2 in the first volunteer. Each volunteers response determines the volume of local anaesthetic for the next volunteer. When sensory block is present within 20 minutes after injection, the volume for the next volunteer is decreased by 0.04 ml/mm^2. Conversely, when sensory block is insufficient, the volume for the next volunteer is increased by th same amount. After three cycles of dose reduction - dose augmentation the ED50 and ED 95 values will be calculated.

After the intervention, volunteers were controlled until total reversal of the block - that means 3 - 6 hours.

#### Intervention Type

Drug

#### Phase

Not Applicable

#### Drug/device/biological/vaccine name(s)

Mepivacaine

#### Primary outcome(s)

Block success: complete sensory block within 20 minutes in the skin area of the blocked ulnar nerve tested by pinprick.

#### Key secondary outcome(s))

Duration of block

#### Completion date

31/12/2006

# **Eligibility**

#### Key inclusion criteria

- 1. Healthy volunteers
- 2. Aged more than 18 and less than 70 years

#### Participant type(s)

Healthy volunteer

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Upper age limit

70 years

#### Sex

All

#### Total final enrolment

17

#### Key exclusion criteria

- 1. Pregnancy
- 2. Sensory or motor abnormalities of the arm
- 3. Alcohol abuse
- 4. Intake of psychotropic drugs
- 5. Allergies to local anaesthetics
- 6. Intake of non-steroidal anti-inflammatory drugs the week preceding the study
- 7. Coagulation abnormalities
- 8. Coronary artery disease
- 9. Bacterical infection, systemic or local
- 10. Fever

#### Date of first enrolment

# Date of final enrolment 31/12/2006

### Locations

#### Countries of recruitment

Switzerland

# Study participating centre University of Bern

Bern Switzerland 3010

# Sponsor information

#### Organisation

University of Bern

#### **ROR**

https://ror.org/02k7v4d05

# Funder(s)

#### Funder type

University/education

#### **Funder Name**

Universität Bern

#### Alternative Name(s)

UniBE, Universität Bern, Université de Berne, Universitas Bernensis, , UB

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

Universities (academic only)

#### Location

#### Funder Name

Swiss Society of Anaesthesiology and Reanimation (SGAR) (Switzerland) - scientific fund

# **Results and Publications**

Individual participant data (IPD) sharing plan

IPD sharing plan summary

**Study outputs** 

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2009	06/08/2021	Yes	No