

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

<b>Submission date</b> 19/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/08/2021	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Urs Eichenberger

**Contact details**  
Department of Anaesthesiology  
University of Bern  
Inselspital  
Bern  
Switzerland  
3010  
-  
[urs.eichenberger@insel.ch](mailto:urs.eichenberger@insel.ch)

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

## Secondary study design

Non randomised study

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## 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<sup>2</sup> 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<sup>2</sup>. Conversely, when sensory block is insufficient, the volume for the next volunteer is increased by the 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 measure**

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

**Secondary outcome measures**

Duration of block

**Overall study start date**

01/08/2006

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

70 Years

**Sex**

Both

**Target number of participants**

20

**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**

01/08/2006

**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

**Sponsor details**

Department of Anaesthesiology

Inselspital

Bern  
Switzerland  
3010

**Sponsor type**

University/education

**Website**

<http://www.unibe.ch/eng/>

**ROR**

<https://ror.org/02k7v4d05>

## Funder(s)

**Funder type**

University/education

**Funder Name**

Universität Bern

**Alternative Name(s)**

Universität Bern, Université de Berne, Universitas Bernensis, UniBE, , Бернски́й університет, Бернски университет, Universitat de Berna, Bernská univerzita, Πανεπιστήμιο της Βέρνης, Universitato de Berno, Universidad de Berna, Berni Ülikool, Bernako Unibertsitatea, , Bernin yliopisto, Univèrsitàt de Bèrna, Universidade de Berna, , Università di Berna, , Берн университеті, , Berno universitetas, Universiteit van Bern, Universitetet i Bern, Бернский университет, Bern Üniversitesi, Берн университеты, Бернський університет, , UB

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Switzerland

**Funder Name**

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

## Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		01/05/2009	06/08/2021	Yes	No