

Evaluation of mepivacaine ED95 for peripheral nerve blocks using ultrasound guidance

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

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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/mm² 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/mm². 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(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. Bacterial 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

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

Switzerland

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