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Evaluation of mepivacaine ED95 for peripheral nerve blocks using ultrasound guidance

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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^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 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, , Бернскі ўніверсітэт, Бернски университет, Universitat de Berna, Bernská univerzita, Πανεπιστήμιο της Βέρνης, Universitato de Berno, Universidad de Berna, Berni Ülikool, Bernako Unibertsitatea, , Bernin yliopisto, Univèrsitât 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?
Results article		01/05/2009	06/08/2021	Yes	No