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Comparison of bupivacaine and lidocaine with epinephrine for digital nerve blocks

Submission date 31/03/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/04/2008	**Overall study status** Completed	
Last Edited 11/05/2009	**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
2061015

Study information

Scientific Title

Study objectives
In this study, we are comparing bupivacaine versus lidocaine with epinephrine when used for the digital block in healthy volunteers aiming to know if there is a difference in the pain of injection. Time of onset and duration of action will also be recorded and compared between the two local anaesthetics.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. The Clinical Research Committee of King Faisal Specialist Hospital and Research Center, Riyadh (Saudi Arabia) on the 17th May 2006 (proposal no.: 2061015)
2. The Research Ethics Committee of King Faisal Specialist Hospital and Research Center, Riyadh (Saudi Arabia) on the 12th June 2006

The reference number at the Office of Research Affair at King Faisal Specialist Hospital and Research Center, Riyadh (Saudi Arabia) is ORA/0642/27.

Study design
Single-centre randomised, double-blinded, prospective study with a single self-controlled arm

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Injection pain in digital nerve blocks

Interventions
1. Bupivacaine 0.5% (4 ml for each digit)
2. Lidocaine 1% with 1:100,000 epinephrin (4 ml for each digit)

Both anaesthetics were adminstered in either the right or left middle finger based on the randomisation table and each participant recieved both anaesthetics in either hand so each participant acts as a self-control to compare the pain of injection. All participants were blinded to which anaesthetics were going in each hand.

The total duration will be until the return of sensation and this will be followed by a 24-hour follow-up.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Bupivacaine, lidocaine, epinephrine

Primary outcome measure
The primary outcome was the pain of injection, and it was measured using a 0- to 100-mm visual analog scale (VAS).

Secondary outcome measures
1. The time in minutes from injection until anaesthesia, measured using testing needle pinpricks
2. The time in minutes from injection until return of sensation, measured using testing needle pinpricks

Overall study start date
27/08/2006

Completion date
28/08/2006

Eligibility

Key inclusion criteria
1. Healthy volunteers more than 18 years of age, either sex
2. No history of cardiovascular or liver disease
3. Not diabetic
4. No history of peripheral vascular disease
5. Not on any current medication
6. Has not taken analgesia within last 48 hours
7. Hasn't had any previous procedures conducted on both hands
8. No previous hand illness (e.g., Raynaud's disease)
9. No known allergies

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
12

Key exclusion criteria
Does not meet above inclusion criteria.

Date of first enrolment
27/08/2006

Date of final enrolment
28/08/2006

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
P.O. Box 230691
Riyadh
Saudi Arabia
11321

Sponsor information

Organisation
King Faisal Specialist Hospital and Research Center (Saudi Arabia)

Sponsor details
P.O. Box 3354
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weam@kfshrc.edu.sa

Sponsor type
Hospital/treatment centre

Website
http://bportal.kfshrc.edu.sa/wps/portal/bportal

ROR
https://ror.org/05n0wgt02

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
King Faisal Specialist Hospital and Research Centre (Saudi Arabia)

Alternative Name(s)
King Faisal Specialist Hospital

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Saudi Arabia

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	results	01/05/2009		Yes	No