

Comparison of bupivacaine and lidocaine with epinephrine for digital nerve blocks

Submission date 31/03/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/04/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/05/2009	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

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 administered in either the right or left middle finger based on the randomisation table and each participant received 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

Riyadh

Saudi Arabia

11211

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