

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effectiveness of Lidocain, Lidocain + Dexmedetomidine and Lidocain + Meperidin on characteristics of Forearm modified Bier's block (F.M.B.B.) in patient with distal forearm trauma (laceration and fracture)

Protocol summary

Study aim

Evaluation and Comparison of the effectiveness of : Lidocain (L) , L + Dexmedetomidine , L + Meperidin on characteristics of Forearm modified Bier's block (F.M.B.B.) in patient with distal forearm trauma (laceration and fracture) .

Design

The study is randomized, double blind clinical trial. In this study 90 eligible patients candidates for wrist and hand surgery will be divided into three parallel groups and a code will be assigned to each patient.

Settings and conduct

The research will be conducted at Sanandaj Kawsar Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: signing written informed consent; ASA (American Society of Anesthesiologist) score 1- 3; age >18 years. Exclusion criteria: History of allergy to the study drugs : thalassaemia; hypertension and cardiovascular diseases.

Intervention groups

Intervention group 1: Lidocain 100 mg (0.5 %) which is increased to volume 20 CC by normal saline (N/S).
Intervention group 2 : Meperidin 0.1 mg / kg + Lidocain 100 mg (0.5 %) which is increased to volume 20 CC by normal saline (N/S). Intervention group 3 :
Dexmedetomidine, 1 microgram / kg + Lidocain 100 mg (0.5 %) which is increased to volume 20 CC by normal saline (N/S).

Main outcome variables

Sensory block without motor block in dependent traumatized limb.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170823035874N2**

Registration date: **2018-06-20, 1397/03/30**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-20, 1397/03/30**

Update count: **0**

Registration date

2018-06-20, 1397/03/30

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3324 1829

Email address

kamalgaderi@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-11, 1396/10/21

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Lidocain, Lidocain +

Dexmedetomidine and Lidocain + Meperidin on characteristics of Forearm modified Bier's block (F.M.B.B.) in patient with distal forearm trauma (laceration and fracture)

Public title
Effect of different drugs on Forearm modified Bier's block (F.M.B.B.)

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age > 18yrs Informed consent The site of surgery be Distal of forearm physical status 1-3 according to American society anesthesiologists (ASA)
Exclusion criteria:
 History of HTN, CVA and Cardiovascular diseases. History of allergy to study drugs Thalassemia

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomisation will be done by one of researchers who is not involved in patient evaluation and anesthesia procedure. This will be done based on computer-generated-numbers. So, we would have 90 envelopes numbered from 1 to 90, and we will put a folded sheet contain the name of one of 3 study groups, so that it can't be read from outside. Based on the number on the sheet inside serial envelopes, patients will enter to one of 3 study groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patients will be divided to 3 groups consisted of 30 patients in each. Researcher and patients are both blind to drugs will be used and the groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Kurdistan University of Medical Sciences

Street address

Faculty of Medicine, Pasharan Blvd

City

Sanandaj

Province

Kurdistan

Postal code

6618634683

Approval date

2017-11-12, 1396/08/21

Ethics committee reference number

IR.MUK.REC.1396.259

Health conditions studied

1

Description of health condition studied

Comparison of the effectiveness of : Lidocain (L) , L + Dexmedetomidine , L + Meperidin on characteristics of Forearm modified Bier's block (F.M.B.B.) in patient with distal forearm trauma (laceration and fracture) .

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sensory block

Timepoint

6 hours-12 hours and 24 hours after surgery

Method of measurement

Bromage Scale

Secondary outcomes

1

Description

Post operative pain

Timepoint

24 hours after surgery

Method of measurement

Based on Pain Visual Analogue Scale (VAS) which is a scale for measurement the intensity of pain .

Intervention groups

1

Description

In the first intervention group, 100 mg lidocain without additive adjuvant (volume increased to 20 CC by N/S) will be injected from specific angiocath inserted to distal

injured limb , in supine position.

Category

Treatment - Drugs

2

Description

Intervention group 2 : 100mg lidocain + 1 microgram / kg dexmedetomidine (volume increased to 20 CC by N/S) will be injected from specific angiocath inserted to distal injured limb , in supine position

Category

Treatment - Drugs

3

Description

Intervention group 3 : 100mg lidocain + 0.1 mg/kg meperirdin (volume increased to 20 CC by N/S) will be injected from specific angiocath inserted to distal injured limb , in supine position

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kawsar hospital

Full name of responsible person

Behzad Ahsan

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Pasdarán Blvd.

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Email

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Web page address

<http://www.muk.ac.ir/Muk/Hospitals/kawsar.aspx>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Farzin Razaee

Street address

Pasdarán Blv.

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Web page address

http://research.muk.ac.ir/_Pages/Default.aspx

Grant name

IR.MUK.REC-1396/259

Grant code / Reference number

IR.MUK.REC-1396/259

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kurdistan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Karim Naseri

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Position

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Specialist

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<http://www.muk.ac.ir/Muk/Faculties/pezeshki.aspx>

Person responsible for updating data

Contact

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Kamal Ghaderi

Position

Resident of anesthesia

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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kamalghaderi@muk.ac.ir

Web page address

<http://www.muk.ac.ir/Muk/Faculties/pezeshki.aspx>

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data s including primary and secondary outcomes , study results , and method of analysis will be published at the end of study.

When the data will become available and for how long

21.11.2018

To whom data/document is available

Under which criteria data/document could be used

Under which criteria data/document could be used

All scholars and academic centers could request access to data and will be able to use it , if mentioning the source.

From where data/document is obtainable

Karim Nasser, Department of Anesthesia. Kasar Hospital , Pasdaran BLVD. Sanandaj, Iran. Tel:00988733660733
Email : bihoshi@gmail.com

What processes are involved for a request to access data/document

We will try to answer to all requests s for data s in two week.

Comments