Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Comparison of the effect of diphenhydramine with injectable lidocaine in median nerve block in patients coming to Imam Khomeini emergency department

Protocol summary

Study aim
Comparison of the effect of diphenhydramine with injectable lidocaine in median nerve block in patients coming to Imam Khomeini

Design
Clinical trial including control group, with factorial groups, triple blinded, randomised

Settings and conduct
This study is performed on patients coming to Imam Khomeini emergency department with a hand laceration. Blinding is performed in a triple blinded method. The researcher injects blindly. The project executor prepares medicines and they are put in the same syringes and they are given to the assistant with A, B and C. Independent variables are the type of anesthesia and its concentration. And dependent variables are side effects of anesthesia and the amount of pain caused by injection. The pain assessment is by using Visual analog scale. Then data will be analyzed by statistical methods.

Participants/Inclusion and exclusion criteria
Entry requirements: Patients between 16 and 65 years with hand laceration; Exit conditions: Patients over 65 and under 16 years old, Those who are allergic to diphenhydramine or lidocaine, those who receive any systemic anesthesia, those who receive MAO inhibitor

Intervention groups
A group: Control group who receive lidocaine. B group: Those who receive diphenhydramine 1%. C group: Those who receive diphenhydramine 0.5%.

Main outcome variables
Duration of medicine effect, onset of action, the amount of pain and side effects

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190318043088N1**
Registration date: **2019-04-22, 1398/02/02**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-22, 1398/02/02**
Update count: **0**

Registration date
2019-04-22, 1398/02/02

Registrant information

Name
fariba yazdanbakhsh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 6656 3818

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fyazdanbakhsh@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-26, 1397/05/04

Expected recruitment end date
2019-06-25, 1398/04/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of diphenhydramine with injectable lidocaine in median nerve block in patients

coming to Imam Khomeini emergency department

Public title
Comparison of the effect diphenhydramine with injectable lidocaine in median nerve block
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The patients coming to the emergency with hand laceration from 16 to 65 years
Exclusion criteria:
The patients under the age of 16 and over 65 People who are allergic to diphenhydramine or lidocaine or they had conractagonism for lidocaine or diphenhydramine Patients who had received any systemic pain killer patients who had received MAO inhibitor
Age
From **16 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **204**
Randomization (investigator's opinion)
Randomized
Randomization description
Selection of the sample is based on the method of the random block. Thus, the first group, A, the second group, B and the third group, C are considered based on the blocks designed and the following 25 blocks 6 randomly selected from the blocks below, all patients from the number 1 Up to 204 are coded according to one of three words A, B or C. The coding is done randomly by the supervisor of the design, and the project manager, the patient and the analyst of the results of the codes do not know anything about codes.
ABABCC/AABCBC/ABBCAC/AACBCB/CCAABB/CCBBAA/CABACB/BBAACC/CBCBAA/ABCABCCABCAB/BBCCAA/ACBACB/CABCAB/BBCACA/CAABBC/CABCBA/ACBBCA/BACBAC/AABBCC
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, the researcher, manager, nurses and the data analyzer are kept blindness. Totally there are three groups. The first group will receive lidocaine 1%, the second group receive diphenhydramine 1% and the third group will receive diphenhydramin 0.5%. The method of blinding is triple blinding. The researcher inject medicine blindly. The medications will be prepared by the supervisor of project and taken to similar syringes and given to the assistant with A, B and C.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Imam Khomeini hospital complex, Tehran university of Medical Sciences
Street address
Doctor Gharib Av., the end of Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1419733141
Approval date
2018-07-22, 1397/04/31
Ethics committee reference number
IR.TUMS.IKHC.REC.1397.095

Health conditions studied

1

Description of health condition studied
Hand laceration
ICD-10 code
S64.1
ICD-10 code description
Injury of median nerve at wrist and hand level

Primary outcomes

1

Description
Duration of medicine effect
Timepoint
After the injection of the medicine when the anesthetic begins until the anesthetic ends
Method of measurement
Chronometer

2

Description
Onset of action of medicine
Timepoint
Immediately after the injection of the medicine
Method of measurement
Chronometer

Secondary outcomes

1

Description
Side effects of medicine
Timepoint
After injection
Method of measurement
Patient Clinic and Previous Studies

2

Description
The amount of pain
Timepoint
While injecting medicine
Method of measurement
Visual analog scale

Intervention groups

1

Description
Control group: Those who receive lidocaine 1%, 3 milliliter, one time, injection, manufacturing factory Caspian
Category
Treatment - Drugs

2

Description
The first intervention group: Those who receive diphenhydramine 1%. , 3 milliliter, one time, injection, manufacturing factory Caspian
Category
Treatment - Drugs

3

Description
The second intervention group: Those who receive diphenhydramine 0.5%. , 3 milliliter, one time, injection, manufacturing factory Caspian
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emergency department of Imam Khomeini hospital complex
Full name of responsible person
Fariba Yazdanbakhsh
Street address
Doctor Gharib Ave., The end of Keshavarz Blvd.
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Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Seyed Ahmad Rezaii
Street address
Doctor Gharib Ave., The end of Keshavarz Blvd.
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Fax
+98 21 8163 3047
Email
Imamhospital@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Fariba Yazdanbakhsh
Position

Resident
Latest degree
Medical doctor
Other areas of specialty/work
Emergency Medicine
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Person responsible for updating data

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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
The total individual data of the participants will be shared after being unidentifiable.
When the data will become available and for how long
Six months after publishing results
To whom data/document is available
Doctors, dentists and researchers working in universities and academic institutes
Under which criteria data/document could be used
If someone wants to do a research related to this study, he or she can use documentation with the ethical requirements
From where data/document is obtainable
Applicants can receive documentation from the author of the article through this email: faribayazdan@yahoo.com
What processes are involved for a request to access data/document
Applicants should refer to emergency department of Imam Khomeini hospital with identification card. And after confirmation, they can apply in writing. Then documentation will send them through email.
Comments