

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of the effect of lidocaine-bicarbonate, lidocaine-dexamethasone and lidocaine alone for digital block in patients with figure injury: a double blind randomized clinical trial

Protocol summary

Summary

Objectives: To compare the effect of lidocaine-bicarbonate, lidocaine-dexamethasone and lidocaine alone for digital block in patients with figure injury.

Design: A double blind randomized clinical trial. Setting and conduct: The eligible patients with finger injury who will refer to Besat Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 18 to 65 years; figure injury. Exclusion criteria: Musculoskeletal disorder. Intervention group 1: Injection of lidocaine 2%, 2 ml and bicarbonate 1 ml, single dose, in the proximal area between the webs of fingers. Intervention group 2: Injection of lidocaine 2%, 2 ml and dexamethasone 1 ml, single dose, in the proximal area between the webs of fingers. Intervention group 3: Injection of lidocaine 2%, 2 ml, single dose, in the proximal area between the webs of fingers. Primary outcome: Assessing the anesthesia 10 minutes after injection through physical examination and taking history. Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201709199014N186**
Registration date: **2017-10-17, 1396/07/25**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-17, 1396/07/25

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2017-05-28, 1396/03/07

Expected recruitment end date

2018-05-28, 1397/03/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of lidocaine-bicarbonate, lidocaine-dexamethasone and lidocaine alone for digital block in patients with figure injury: a double blind randomized clinical trial

Public title

Comparison of the effect of lidocaine-bicarbonate,

lidocaine-dexamethasone and lidocaine alone for digital block in patients with figure injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 65 years; figure injury.

Exclusion criteria: Musculoskeletal disorder.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

Approval date

2017-05-27, 1396/03/06

Ethics committee reference number

IR.UMSHA.REC.1396.152

Health conditions studied

1

Description of health condition studied

Figure injury

ICD-10 code

S64.4

ICD-10 code description

Injury of digital nerve of other finger

Primary outcomes

1

Description

Assessing the anesthesia

Timepoint

10 minutes after injection

Method of measurement

Through physical examination and taking history

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Injection of lidocaine 2%, 2 ml and bicarbonate 1 ml, single dose, in the proximal area between the webs of fingers.

Category

Treatment - Drugs

2

Description

Intervention group 2: Injection of lidocaine 2%, 2 ml and dexamethasone 1 ml, single dose, in the proximal area between the webs of fingers.

Category

Treatment - Drugs

3

Description

Intervention group 3: Injection of lidocaine 2%, 2 ml, single dose, in the proximal area between the webs of fingers.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Dr Mahmood Rezaei

Street address
Besat Hospital, Shahed Square
City
Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave
City
Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for Research and Technology, Hamadan
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
Besat Hospital
Full name of responsible person
Dr Mahmood Rezaei
Position
Anesthesiologist
Other areas of specialty/work
Street address
Besat Hospital, Shahed Square
City
Hamadan
Postal code
Phone
+98 81 3364 0030
Fax
Email
mrezaei1961@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Besat Hospital
Full name of responsible person
Dr Mahmood Rezaei
Position
Anesthesiologist
Other areas of specialty/work
Street address
Besat Hospital, Shahed Square
City
Hamadan
Postal code
Phone
+98 81 3364 0030
Fax
Email
mrezaei1961@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Department of Epidemiology
Full name of responsible person
Dr Jalal Poorolajal
Position
Associate Professor
Other areas of specialty/work
Street address
School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code
Phone
+98 81 3838 0090
Fax
Email
poorolajal@umsha.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty