

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of the effectiveness of adding bicarbonate in anesthesial effect of lidocain

Protocol summary

Study aim

Compromise of anesthesial time of lidocain and lidocain plus bicarbonate in one cm of laceration

Design

Randomized double parallel group trial with double blind injection of lidocain and lidocain plus bicarbonate in anesthesy of laceration belowe 10 cm and distal to knee and elbow

Settings and conduct

In patient that have laceration belowe 10 cm and distal knee and elbow that will recipte into khatam hospital of zahedan will inject lidocain which maybe have bicarbonate in double blind method and compromise two group in time of begining and period time of anesthesy

Participants/Inclusion and exclusion criteria

Patient with laceration belowe 10 cm and belowe knee and elbow without crush amputation severe bleeding and neurovascular injury

Intervention groups

Adding of bicarbonate in injection of lidocain in interventional group and injection of lidocain in control group

Main outcome variables

The time of begining and period time of anesthesy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190430043435N1**

Registration date: **2019-06-29, 1398/04/08**

Registratation timing: **registered_while_recruiting**

Last update: **2019-06-29, 1398/04/08**

Update count: **0**

Registration date

2019-06-29, 1398/04/08

Registrant information

Name

Islamic republic of iran Sargolzaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3322 0501

Email address

farhadsargol@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of adding bicarbonate in anesthesial effect of lidocain

Public title

Increase anesthesial effect of lidocain with adding bicarbonate

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Laceration less than10 cm Distal to elbow and knee

Exclusion criteria:

Neurovascular injury of DM or CHF or trauma Crush and amputation Massive bleeding History of sensitivity to lidocain

Age

From 14 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blocking of patient with convenience sampling into 6 block 4some with used of random numbers tablet

Blinding (investigator's opinion)

Double blinded

Blinding description

Providing of half of vial of lidocain with add of bicarbonate that every patient use from one soluble and not only patient nor phisition know the kind of anesthetic drug, from injection to calculation of time of anesthesia ,of course we will get from all of patient the informed consent form and give them information from study for safty of study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

Jamejam

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9654367867

Approval date

2018-06-17, 1397/03/27

Ethics committee reference number

IR.ZAUMS.REC.1397.151

Health conditions studied

1

Description of health condition studied

Laceraton belowe 10cm distal knee and elbow

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Local anesthetic time

Timepoint

First begining of anesthesia and end of it

Method of measurement

Timing of begining to end of it in assess of minute

Secondary outcomes

1

Description

Anesthesial begining time and end

Timepoint

Begining of local injection .begining of anesthesia.end of anesthesia

Method of measurement

In base of minute

Intervention groups

1

Description

In interventional group we inject from lidocain plus bicarbonate(10to1)in amount of one cc in one cm2 of lesion and we will find the time of begin and end of anesthesi with cronometer.

Category

Treatment - Drugs

2

Description

Control group:in contrl group we inject only lidocain into lesion in amount of one cc in one cm2 of lesion

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan khatam hospital

Full name of responsible person

Dr jalal sargolzaei

Street address

Jamejam

City

Zahedan
Province
Sistan-va-Balouchestan
Postal code
9815733169
Phone
+98 54 3322 3001
Email
Farhadsargol@zaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Jalal sargolzaei
Street address
jamejam
City
zahedan
Province
Sistan-va-Balouchestan
Postal code
0943329809
Phone
+98 54 3322 1001
Email
farhadsargol@gmail.com
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan University of Medical Sciences
Proportion provided by this source
1
Public or private sector
Private
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
Zahedan University of Medical Sciences
Full name of responsible person
Jalal sargolzaei
Position
Assistant of emergency medicine
Latest degree
Medical doctor

Other areas of specialty/work

Emergency Medicine
Street address
Jamejam
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9815733169
Phone
+98 0543223001
Email
Farhadsargol@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Jalal sargolzaei
Position
Assistant of emergency medicine
Latest degree
Medical doctor
Other areas of specialty/work
Emergency Medicine
Street address
Jamejam
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9815733169
Phone
+98 0543223001
Email
Farhadsargol@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Jalal sargolzaei
Position
Assistant of emergency medicine
Latest degree
Medical doctor
Other areas of specialty/work
Emergency Medicine
Street address
Jamejam
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code

۹۸۱۵۷۳۳۱۶۹

Phone

+98 0543223001

Email

Farhadsargol@gmail.com

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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The time of anesthesia is the power of drug that used for procedure

When the data will become available and for how long

From end of study

To whom data/document is available

All of researching and industrial agent

Under which criteria data/document could be used

After reliable and reasonable results mean that bicarbonate add lidocain have increasing painless result

From where data/document is obtainable

The investigation responsible with address in irtc

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

Email of proposal paper

Comments