Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigation of the effect of local anesthesia with epinephrine (with Inferior Alveolar Nerve Block anesthesia technique) on blood pressure of people applying for tooth extraction

Protocol summary

Study aim

Determining the effect of local anesthesia with epinephrine on blood pressure of candidates for tooth extraction using the Inferior Alveolar Nerve Block anesthesia technique

Design

Two arm parallel group double blinded randomised trial phase 3 on 40 participants that STATA software is used for randomization.

Settings and conduct

In order to obtain complete anesthesia, two Lidocaine carpoles or two Citanest carpoles will be infusioned. In order to reduce the operating error, all injections will be performed by one person. The type of injection in these people will be alveolar inferior nerve block after negative aspiration. Systolic and diastolic blood pressure and heart rate in each patient are measured in four stages by another person who is unaware of the type of anesthesia. 1. After the patient sits in a chair for 5 minutes. 2. After the injection, the patient was completely anesthetized. 3. At the end of the operation after the tooth is removed. 4. Finally in 5 minutes after surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria in this study 1. All patients referred to the surgical department of Bandar Abbas Dental School 2. Patients have no systemic problems and have general health. Exclusion criteria in this study 1. Patients who are reluctant to cooperate, 2. Patients with cardiovascular problems, 3. Patients with uncontrolled blood pressure, and 4. Patients with uncontrolled hyperthyroidism.

Intervention groups

First intervention group: In this group, local anesthesia of Inferior Alveolar Nerve Block will be used using lidocaine along with epinephrine. Second intervention group (Control): In this group, local anesthesia of Inferior Alveolar Nerve Block will be used using Citanest drug (lidocaine without epinephrine).

Main outcome variables

Systolic blood pressure Diastolic blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200705048014N1**
Registration date: **2020-08-21, 1399/05/31**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-21, 1399/05/31**
Update count: **0**

Registration date

2020-08-21, 1399/05/31

Registrant information

Name

Mohammad Reza Moaddeli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3335 0458

Email address

m.moaddeli@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of local anesthesia with epinephrine (with Inferior Alveolar Nerve Block anesthesia technique) on blood pressure of people applying for tooth extraction

Public title

Investigation of the effect of local anesthesia with epinephrine on blood pressure of people applying for tooth extraction

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have referred for tooth extraction and use Inferior Alveolar Nerve Block anesthesia for anesthesia Patients who have no systemic problems and are in good general health.

Exclusion criteria:

Patients who do not want to cooperate. Patients with cardiovascular problems. Patients with uncontrolled blood pressure. Patients with uncontrolled hyperthyroidism.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Stochasticization process In this study, quadruple blocks are randomly divided into two groups. One group receiving anesthesia containing epinephrine and one group receiving anesthesia without epinephrine. Randomization is done in individual units using STATA software and Block Randomization method.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient is not informed of the medication to be taken and the anesthetic carpole is placed in the injection syringe before the patient is present and the evaluator is not aware of the type of anesthetic injection.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Bandar Abbas University of Medical Sciences

Street address

Ethics Committee of Bandar Abbas University of Medical Sciences,Research Deputy Building, Shahid Mohammadi Hospital, Jomhoori Islami Blvd.

City

Bandar Abbas

Province

Hormozgan

Postal code

7916613885

Approval date

2020-01-14, 1398/10/24

Ethics committee reference number

IR.HUMS.REC.1398.389

Health conditions studied

1

Description of health condition studied

Blood-pressure

ICD-10 code

R03.0

ICD-10 code description

Elevated blood-pressure reading, without diagnosis of hypertension

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

Systolic blood pressure is measured in four stages. 1- Five minutes before the anesthetic injection. 2- Immediately after anesthesia injection. 3- Immediately after the tooth is removed. 4- Five minutes after the tooth is removed.

Method of measurement

Systolic blood pressure is measured in each patient at all four stages by a dentist who does not know the type of anesthesia using a calibrated EmSig sphygmomanometer.

2

Description

Diastolic blood pressure

Timepoint

Diastolic blood pressure is measured in four stages. 1- Five minutes before the anesthetic injection. 2- Immediately after anesthesia injection. 3- Immediately after the tooth is removed. 4- Five minutes after the tooth is removed.

Method of measurement

Diastolic blood pressure is measured in each patient at all four stages by a dentist who does not know the type of anesthesia using a calibrated EmSig sphygmomanometer.

3

Description

Heart rate

Timepoint

Heart rate is measured in four stages. 1- Five minutes before the anesthetic injection. 2- Immediately after anesthesia injection. 3- Immediately after the tooth is removed. 4- Five minutes after the tooth is removed.

Method of measurement

Heart rate is measured in each patient at all four stages by a dentist who does not know the type of anesthesia using an EmSig stethoscope.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group were injected with two carpools of lidocaine containing 108 mg of lidocaine and 0.054 mg of epinephrine for local anesthesia.

Category

Other

2

Description

Control group: Patients in this group are injected with two carpooles of Citanest containing 162 mg of Citanest for local anesthesia.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental Clinic of Bandar Abbas Faculty of Dentistry

Full name of responsible person

Mohammad Reza Moaddeli

Street address

Dental Clinic of Bandar Abbas School of Dentistry, Shahid Naser St, Imam Khomeini Blvd

City

Bandar Abbas

Province

Hormozgan

Postal code

7914964153

Phone

+98 76 3335 0458

Email

hums@hums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Teamour Aghamolai

Street address

Shahid Mohammadi Hospital, Jomhouri Islami St, Imam Khomeini Blvd

City

Bandar Abbas

Province

Hormozgan

Postal code

7919915519

Phone

+98 76 3334 5009

Email

taghamolaei@hums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Mohammad Reza Moaddeli

Position

Assistant Professor

Latest degree

Specialist
Other areas of specialty/work
Dentistry
Street address
Imam Khomeini Blvd.
City
Badar Abbas
Province
Hormozgan
Postal code
7919915519
Phone
+98 76 3335 0458
Fax
Email
m.moaddeli@hums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Mohammad Reza Moaddeli
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Imam Khomeini Blvd.
City
Badar Abbas
Province
Hormozgan
Postal code
7919915519
Phone
+98 76 3335 0458
Fax
Email
m.moaddeli@hums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Hadis Ansari
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
Imam Khomeini Blvd.
City
Badar Abbas
Province
Hormozgan
Postal code
7919915519
Phone
+98 76 3335 0458
Fax
Email
vania-f@yahoo.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
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 information from this study can be shared without identifying participants.
When the data will become available and for how long
2021/3/21
To whom data/document is available
Researchers and referees
Under which criteria data/document could be used
Obtaining a written permit and mentioning the name in the sources and references
From where data/document is obtainable
Dr. Mohammad Reza Moaddeli m.moaddeli@hums.ac.ir
What processes are involved for a request to access data/document
The request must first be emailed and answered after review and approval.
Comments