

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Hemodynamic changes after administration of 2% lidocaine with 1:100,000 epinephrine compared to 4% articaine with 1:100,000 epinephrine: prospective, double-blinded, randomized clinical trial

Protocol summary

Study aim

To compare hemodynamic changes after administration of 2% lidocaine with 1:100,000 epinephrine and 4% articaine with 1:100,000 epinephrine

Design

A prospective, parallel-group, double-blinded, randomized controlled trial

Settings and conduct

Patients who required surgical extraction of wisdom teeth were randomly allocated to 2 intervention groups. patient and surgeon were blinded to the intervention and investigator collected data according to the number of an envelope containing intervention.

Participants/Inclusion and exclusion criteria

Healthy patients with blood pressure below 140/90

Intervention groups

patients who received 4% articaine with 1:100,000 epinephrine

Main outcome variables

hemodynamic change

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180330039161N2**

Registration date: **2019-08-04, 1398/05/13**

Registration timing: **prospective**

Last update: **2019-08-04, 1398/05/13**

Update count: **0**

Registration date

2019-08-04, 1398/05/13

Registrant information

Name

Saeid Tavanafar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3230 6655

Email address

Tavanafar@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-12, 1398/06/21

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Hemodynamic changes after administration of 2% lidocaine with 1:100,000 epinephrine compared to 4% articaine with 1:100,000 epinephrine: prospective, double-blinded, randomized clinical trial

Public title

Hemodynamic effects of 2% lidocaine with 1:100,000 epinephrine compared to 4% articaine with 1:100,000 epinephrine

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

ASA 1 and 2 Level A and Class I Pell and Gregory classification of impacted mandibular third molars

patients who weren't diagnosed as hypertensive and their blood pressure <140/90 mm Hg

Exclusion criteria:

hypertension cardiovascular disease sickle cell anemia congenital methemoglobinemia pregnancy hyperthyroidism breastfeeding allergy to local anesthetics any contraindications to epinephrine if the extraction required more than 2 local anesthetic cartridges the duration exceeded 45 minutes

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The simple method of randomization sequentially numbered, opaque, sealed envelopes with random sequence in a way that surgeon and patients would be blinded of the anesthetic used

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant and surgeon were blinded by sequentially numbered, opaque, sealed envelopes containing either of the 2 interventions. Investigator then used the data for statistical analysis using the numbered envelope which was associated with each intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

No 2, felestin Ave, Zand Boulevard

City

Shiraz

Province

Fars

Postal code

7134647637

Approval date

2019-06-09, 1398/03/19

Ethics committee reference number

IR.SUMS.REC.1398.516

Health conditions studied

1

Description of health condition studied

Impacted mandibular third molar

ICD-10 code

T49.7X6A

ICD-10 code description

Underdosing of dental drugs, topically applied, initial encounter

Primary outcomes

1

Description

Hemodynamic change

Timepoint

Before surgery, after anesthetic injection, after surgical removal of the impacted third molars

Method of measurement

pulse oximetry, electronic sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients candidate of surgical removal of mandibular third molar removal received two capules of 1.8 mg of 4% articaine with 1:100,000 epinephrine to anesthetize the surgical site.

Category

Treatment - Drugs

2

Description

Control group: Patients in control group recieved the routine anesthetic solution of two carpules of 1.8mg of 2% lidocaine with 1:100,000 epinephrine.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry, Shiraz University of Medical Sciences

Full name of responsible person

Saeid Tavanafar

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No. 2, felestin street, Zand boulevard

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Samira Karanjam

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

10

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**

Shiraz University of Medical Sciences

Full name of responsible person

Saeid Tavanafar

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Saeid Tavanafar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Saeid Tavanafar

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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

Part of data related to variables will be shared

When the data will become available and for how long

starting in January 2020

To whom data/document is available

Academic institutions

Under which criteria data/document could be used

Be part of an academic institution

From where data/document is obtainable

Contact Saeid Tavanafar by Email:

s.tavanafar@gmail.com

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

Proof of academician

Comments