

# 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

**Street address**

No. 2, felestin street, Zand boulevard

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**Postal code**

7134647637

**Phone**

+98 71 3230 6655

**Email**

tavanafar@sums.ac.ir

**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

**Street address**

No 2, felestin street, Zand boulevard

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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**

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Resident

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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**