

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Comparison of the impact of two local anesthesia (Epinephrine containing Lidocaine & Mepivacaine) On glycemic level

#### Protocol summary

##### Study aim

Comparison between the affect of two local anesthesia on glycemic level in order to inform the dentists & surgeons to choose the best local anesthesia that makes the least glucose level change after anesthetic Injection & within the therapeutic procedure.

##### Design

Clinical trial with control group, Society based & practical, Double blinded, Randomized

##### Settings and conduct

This study is performed at Surgical Department of Shiraz Dental University. One hundred patients who participate in this research will be divided into two groups of 50 and will be injected randomly with one of these anesthetic agents: Lidocaine or Mepivacaine Injection method is inferior alveolar nerve block. Before the injection, informed consent is signed and filled by the patients. Glucose level is measured before the injection & also 20 minutes after the unjection (before extraction procedure). After all, we analyze glucose level variation across two groups, using statistical approach.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients within the age of 18 to 50 years; Patients who have had breakfast at least one hour ago Exclusion criteria: Patients who have addiction; Diabetic patients (controlled or uncontrolled); Patients who are allergic to local anesthetic agents or NSAIDs; Patients who show allergic reactions after the injection; Highly stressed patients; Patients who show resistance to the injected anesthetic agent and need more than three carpules; Lidocaine contraindication cases

##### Intervention groups

In this study the intervention group is the one in which used anesthesia is Epinephrine containing Lidocaine, the other group in which the used anesthesia is Mepivacaine, is control group

##### Main outcome variables

The glucose level which is measured by glucometer

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181114041651N1**

Registration date: **2022-10-31, 1401/08/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-10-31, 1401/08/09**

Update count: **0**

##### Registration date

2022-10-31, 1401/08/09

##### Registrant information

##### Name

Ehsan Aliabadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3626 3192

##### Email address

aliabadie@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-10-19, 1401/07/27

##### Expected recruitment end date

2022-11-21, 1401/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the impact of two local anesthesia (Epinephrine containing Lidocaine & Mepivacaine) On glycemic level

#### Public title

Comparison of the effect of Epinephrine containing Lidocaine and Mepivacaine on glycemic level

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients within the age of 18 to 50 years Patients who have had breakfast at least one hour ago

##### Exclusion criteria:

Patients who have addiction Diabetic patients (controlled or uncontrolled) Patients who are allergic to local anesthetic agents or NSAIDs Patients who show allergic reactions after the injection Highly stressed patients Patients who show resistance to the injected anesthetic agent and need more than three carpules Lidocaine contraindication cases

#### Age

From **18 years** old to **50 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **100**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Permuted block randomization, in this technique in order to randomize the participants selection, the permuted block method is used. Participants are selected randomly to be injected by the group A & B anesthesia agents. Blocks can be AA,BB AB,AB BA,AB BA,BA &....

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The participant, Outcome assessor, Data analyst

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

#### Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd.

#### City

Shiraz

#### Province

Fars

#### Postal code

713451978

#### Approval date

2022-08-27, 1401/06/05

#### Ethics committee reference number

24766

### Health conditions studied

#### 1

##### Description of health condition studied

Diabetes

##### ICD-10 code

E08

##### ICD-10 code description

Diabetes mellitus due to underlying condition

### Primary outcomes

#### 1

##### Description

Glucose level

##### Timepoint

Before intervention and 20 minutes after the local anesthesia injection

##### Method of measurement

Blood glucose meter

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Control group: The patients who receive Mepivacaine (Epinephrine free) as anesthetic agent

##### Category

Other

#### 2

##### Description

Intervention group: Patients who receive Lidocaine (Containing Epinephrine) as anesthetic agent

##### Category

Other

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Shiraz dentistry faculty

**Full name of responsible person**

Sara Gharabati

**Street address**

Dentistry faculty, Corner of Mehr Blvd., Qasrodasht St.

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dental@sums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Mahtab Memarpour

**Street address**

Vice-Chancellor for research, Shiraz University of Medical Sciences, Zand Blvd.

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**Email**

vcrdep@sums.ac.ir

**Web page address**

<https://research.sums.ac.ir/>

**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**

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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Ehsan Aliabadi

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Maxillofacial surgeon

**Street address**

Corner of Mehr Blvd., Qasrodasht St., Dentistry faculty

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Ehsan Aliabadi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

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Shiraz University of Medical Sciences

**Full name of responsible person**

Ehsan Aliabadi

**Position**

Assistant Professor

**Latest degree**

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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**

After publication of the article, in case of request from academic email, the corresponding author provides the requested information.

**When the data will become available and for how long**

After publication of the article, in case of request from academic email, the corresponding author provides the requested information.

**To whom data/document is available**

After publication of the article, in case of request from academic email, the corresponding author provides the requested information.

**Under which criteria data/document could be used**

After publication of the article, in case of request from academic email, the corresponding author provides the requested information.

**From where data/document is obtainable**

After publication of the article, in case of request from academic email, the corresponding author provides the requested information.

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

After publication of the article, in case of request from academic email, the corresponding author provides the requested information.

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