# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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 recieve Mepivacaine (Epinephrine free) as anesthetic agent
**Category**
Other

**2**

**Description**
Intervention group: Patients who recieve 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

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

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## Sponsors / Funding sources

**1**

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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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Assistant Professor

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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.

**Comments**