

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of effect of articaine with 1:200000 epinephrine on blood glucose in type 2 diabetic and non-diabetic patients.

Protocol summary

Study aim

Determining the change of blood glucose concentration in compared to the basic state in type 2 diabetic patients and non-diabetic patients in 5th and 15th minute after injection.

Design

Clinical trial with control group.with parallel groups. non-blinded. non-randomized. phase 3 on 60 patients.

Settings and conduct

Tooba dental clinic - Sari -Iran. In both groups, the basic level of blood glucose will be measured by a glucometer. Then, while the patient is in semi-supine position, two carpools of articaine 4% with epinephrine 1:200,000 will be injected by infiltration method. For this purpose, the needle will be inserted from the depth of the vestibule and the injection will be performed in the apex area of the desired tooth root. Then, level of blood glucose will be measured.(This study is non-blinded).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who: 1.Do not have any underlying disease or only have type 2 diabetes. 2. Their written consent has been obtained. 3. Their diabetes is controlled. (minimum 70 mg/dl and maximum 180 mg/dl).
Exclusion criteria:Parientis who: 1.Are not suffering from any other underlying disease exept type 2 diabetes. 2. Are without written consent. 3. Their diabetes is not controlled.

Intervention groups

1. Intervention group: Diabetic patients receiving articaine with epinephrine 1:200,000. 2. Control group: non-diabetic patients receiving articaine with epinephrine 1:200,000.

Main outcome variables

Level of blood glucose (5 and 15 minutes after injection of articaine with 1:200000 epinephrine).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230225057537N1**
Registration date: **2023-07-04, 1402/04/13**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-04, 1402/04/13**

Update count: **0**

Registration date

2023-07-04, 1402/04/13

Registrant information

Name

amirhosein akbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 933 989 6968

Email address

amirha8991@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-26, 1402/04/05

Expected recruitment end date

2023-08-01, 1402/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of articaine with 1:200000 epinephrine on blood glucose in type 2 diabetic and non-diabetic patients.

Public title

Comparison of effect of articaine with 1:200000 epinephrine on blood glucose in diabetic and non-diabetic patients.

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who, according to their own report, either do not have any underlying disease or only have type 2 diabetes. Patients who need infiltration anesthesia. Patients with written consent. Patients whose diabetes is controlled. (minimum 70 mg/dl and maximum 180 mg/dl)

Exclusion criteria:

Patients who are suffering from any other underlying disease except type 2 diabetes. Patients who don't need infiltration anesthesia. Patients without written consent. Patients whose diabetes is not controlled.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **3**

Blood glucose will be measured in 3 times. 1 Before injection 2. After 5 minutes of injection. 3. After 15 minutes of injection.

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary IDs**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mazandaran University of Medical Sciences

Street address

Mazandaran university of medical sciences.
Farahabad blvd. Sari. Iran

City

Sari

Province

Mazandaran

Postal code

4749146294

Approval date

2023-02-16, 1401/11/27

Ethics committee reference number

IR.MAZUMS.REC.1401.532

Health conditions studied**1****Description of health condition studied**

Effect of articaine with 1:200000 epinephrine on blood glucose in diabetic and non-diabetic patients.

ICD-10 code

R73.0

ICD-10 code description

Abnormal glucose tolerance test

Primary outcomes**1****Description**

Level of blood glucose

Timepoint

1. Before injection. 2. After 5 minutes of injection 3. After 15 minutes of injection.

Method of measurement

Blood glucose monitoring system (glucometer)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Changes of blood glucose after injection of articaine with 1:200000 epinephrine in type 2 diabetic patients. At first, in group of diabetic patients, the basic level of blood glucose concentration will be measured by a glucometer (before injection). Then, while the patient is in semi-supine position, two carpules of articaine 4% with epinephrine 1:200,000 will be injected by infiltration method. For this purpose, the needle will be inserted from the depth of the vestibule and the injection will be performed in the apex area of the desired tooth root. Blood glucose levels will be measured 5 and 15 minutes after injection.

Category

Treatment - Drugs

2**Description**

Intervention group: Changes of blood glucose after

articaine 1:100000 epinephrine in healthy(non-diabetic) patients. At first in group of non-diabetic patients, the basic level of blood glucose concentration will be measured by a glucometer. Then, while the patient is in semi-supine position, two carpules of articaine 4% with epinephrine 1:200,000 will be injected by infiltration method. For this purpose, the needle will be inserted from the depth of the vestibule and the injection will be performed in the apex area of the desired tooth root. Blood sugar levels will be measured 5 and 15 minutes after injection.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tooba dental clinic

Full name of responsible person

Amirhosein Akbari

Street address

Tooba dental clinic. Sari. Iran

City

Sari

Province

Mazandaran

Postal code

48157-33971

Phone

+98 11 3304 4000

Email

name@domain.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr seyed mahdi taghian

Street address

Mazandaran university of medical sciences. Beggining of valieasr highway. Sari

City

Sari

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Postal code

48157-33971

Phone

+98 11 3304 4000

Email

ravabetoomi@mazums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Mehdi Taghian

Position

assistant professors and faculty member of mazandaran university of medical sciences.

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

office unit 610. 6th floor. shriar3 building . farhang str. sari

City

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Mazandaran

Postal code

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Phone

+98 11 3330 5443

Fax

Email

m.taghian@mazums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Mehdi Taghian

Position

assistant professors and faculty member of mazandaran university of medical sciences.

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Fax**Email**

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

Mazandaran University of Medical Sciences

Full name of responsible person

Amirhosein Akbari

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

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City

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Mazandaran

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4749146294

Phone

+98 933 989 6968

Fax**Email**

amirha8991@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Part of the data such as information of main outcome can be shared

When the data will become available and for how long

Access period starts 6 month after the results are published.

To whom data/document is available

Documents will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The use of data to carry out new research projects is permitted.

From where data/document is obtainable

To the email address of the respondent; Amirhosein Akbari : amirha8991@gmail.com

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

After reviewing the incoming emails, the data will be send to the applicant.

Comments