Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Public title
Comparison of effect of articaine with 1:200000 epinepherine 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 who their diabetes is controlled. (minimum 70 mg/dl and maximum 180 mg/dl)
Exclusion criteria:
Patients who are suffering from any other underlying disease exept type 2 diabetes. Patients who don't need infiltration anesthesia. Patients without written consent. Patients who their 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. 5minutes of injection 3. After15minutes 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 wil 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

Province

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Postal code

48157-33971

Phone

+98 11 3304 4000

Email

ravabetomoomi@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

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Province

Mazandaran

Postal code

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Phone

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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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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
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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 institusions.
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