

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

A comparative onset and duration of anesthetic of articaine 4% with epinephrine 1:100000 and lidocaine 2% with epinephrine 1:80000 with AMSA nerve block in anterior and premolar teeth

Protocol summary

Summary

The aim of this Randomized, Double blind, Cross over clinical trial is comparing the onset and duration of anesthetic effect of Anterior Middle Superior Alveolar (AMSA) nerve block using Articaine 4% with epinephrine 1:100000 and Lidocaine 2% with epinephrine 1:80000 in anterior and premolar teeth. Sixteen male/female volunteers ranging 18 to 65 years old which have at least 3 intact incisors, canine and premolars in each quadrant, including the study. The base line sensitivity of each tooth will determine by electric and cold tests. In first session, the AMSA block will perform by 0.9 ml Lidocaine and after one week the block will repeat by the same volume of Articaine. The onset of anesthesia will consider where both the electric and cold tests respond negatively and every one minute the tests will continue till the positive response to one of the the test regain, and the time will consider for the end of anesthesia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041815782N5**
Registration date: **2017-07-17, 1396/04/26**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-17, 1396/04/26

Registrant information

Name

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative onset and duration of anesthetic of articaine 4% with epinephrine 1:100000 and lidocaine 2% with epinephrine 1:80000 with AMSA nerve block in anterior and premolar teeth

Public title

A comparative efficacy of two anesthetics in teeth anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients between 18 and 65 years; patients with minimum one healthy tooth quadrant
Exclusion criteria: allergy to local anesthetic agents; history of systemic disease; pregnancy and lactation;

take any CNS depressants including alcohol or any analgesic medication within the last 24 h; have pulp and preapical disease; using tobacco products

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **16**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran Medical Science Branch,
Islamic Azad University

Street address

No.4, Neyestan 10 Alley, Pasdaran Street

City

Tehran

Postal code

Approval date

2017-03-12, 1395/12/22

Ethics committee reference number

پ/113/د

Health conditions studied

1

Description of health condition studied

local anesthesia

ICD-10 code

Y48.3

ICD-10 code description

Local anaesthetics

Primary outcomes

1

Description

duration of anesthesia

Timepoint

in one minutes

Method of measurement

minute-hand clock

2

Description

onset of anesthesia

Timepoint

in one minutes after injection

Method of measurement

minute-hand clock

Secondary outcomes

empty

Intervention groups

1

Description

Injection of 0.9 ml Lidocaine 2% with epinephrine
1:80000 with AMSA technique in 60 seconds.

Category

Treatment - Drugs

2

Description

Injection of 0.9 ml Articaine 4% with epinephrine
1:100000 with AMSA technique in 60 seconds.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Medical science Branch, Islamic Azad
University

Full name of responsible person

Sohrab Tour Savadkouhi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran Medical Science Branch, Islamic Azad

University
Full name of responsible person
Nava VakiliNejad
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No.4, Neyestan10 Alley, Pasdaran Street
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran Medical Science Branch, Islamic Azad University
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty