

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effects of articaine and lidocaine anesthetics on blood pressure after maxillary infiltration technique: a randomized clinical trial

Protocol summary

2020-07-27, 1399/05/06

Study aim

to evaluate the effects of 4% articaine with 1:100000 epinephrine and 2% lidocaine with 1:80000 epinephrine on blood pressure after maxillary infiltration technique.

Design

Parallel group, triple blind, randomized clinical trial

Settings and conduct

Sari Dental School, involving maxillary infiltration of local anesthetics. participants, operators, and statistician are blinded

Participants/Inclusion and exclusion criteria

Inclusion criteria were class 1 American Society of Anesthesiologists patients aged 18 to 55 years, not taking any medication, no contraindication for administration of epinephrine -containing anesthetics, non-smoker patients, without dental phobia, without excessive pain or swelling on admission, and not being pregnant. Patients who experienced dental emergencies after injection were excluded from the study.

Intervention groups

lidocaine group: maxillary infiltration of 2% lidocaine with 1:80000 epinephrine articaine group: maxillary infiltration of 4% articaine with 1:100000 epinephrine

Main outcome variables

systolic and diastolic blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200724048188N1**

Registration date: **2020-07-27, 1399/05/06**

Registration timing: **prospective**

Last update: **2020-07-27, 1399/05/06**

Update count: **0**

Registration date

Registrant information

Name

Parisa Soltani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 5508

Email address

parisa.soltani@live.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-10, 1399/07/19

Expected recruitment end date

2020-12-10, 1399/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of articaine and lidocaine anesthetics on blood pressure after maxillary infiltration technique: a randomized clinical trial

Public title

Effects of articaine and lidocaine anesthetics on blood pressure

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

class 1 American Society of Anesthesiologists aged 18 to 55 years not taking any medication no contraindication

for administration of epinephrine non-smoker patients without dental phobia without excessive pain or swelling on admission not being pregnant

Exclusion criteria:

dental emergencies after injection

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned using computer-generated random numbers into two groups (block randomization). We will use random allocation software for this purpose. Random allocation of patient 1 to 102 into two equal groups will be obtained. Patient's number will be assigned based on order of admission (first patient:1, second patient:2, etc.).

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patients and operators are blind to the experimental groups in all stages of the research study. Only one researcher who is present in the surgical room but is unrelated to the experiments and measurements is aware of the experimental group of each patient. After obtaining informed consent, the patients will not know about the group they are in. The researcher who is not blind will prepare the injection syringe based on the random allocation numbers. He will cover the anesthetic cartridge using black tape, so that the operator does not know which drug is being used. The other operator who is measuring blood pressure does not know the patient's group either. The researcher who was not blind will code the experimental groups (1 and 2) so that the statistician is also blind to the experimental groups

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

Valiasr

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2019-06-11, 1398/03/21

Ethics committee reference number

IR.MAZUMS.REC.1398.544

Health conditions studied

1

Description of health condition studied

systolic and diastolic blood pressure

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

systolic and diastolic blood pressure

Timepoint

before intervention, 10 minutes after intervention

Method of measurement

sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: posterior maxillary infiltration injection of 1.2 mL of 4% articaine with 1:100000 epinephrine (Exir, Iran)

Category

Other

2

Description

Intervention group: posterior maxillary infiltration injection of 1.2 mL of 2% lidocaine with 1:80000 epinephrine (Darupakhsh, Iran)

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sari Dental School

Full name of responsible person

Amirhossein Moaddabi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeidi (Research Chancellor)

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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

Amirhossein Moaddabi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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Latest degree

Specialist

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

none

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable