

# 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

**Street address**

Valiasr

**City**

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Mazandaran

**Postal code**

4815733971

**Phone**

+98 11 3335 2725

**Email**

a.moaddabi2@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Majid Saeidi (Research Chancellor)

**Street address**

Valiasr

**City**

Sari

**Province**

Mazandaran

**Postal code**

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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

**Street address**

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**Province**

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**Postal code**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Amirhossein Moaddabi

**Position**

Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

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**Latest degree**

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**Other areas of specialty/work**

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**Email**

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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