

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Clinical trial of evaluation of blood pressure and heart rate by injecting epinephrine containing and without epinephrone local anesthetia

Protocol summary

Summary

This case-control randomized clinical trial without blinding aims to determine the effect of epinephrine containing lidocaine on blood pressure and heart rate of 18 to 45 years old patients referring for surgery for the permanent teeth. In case of cardiovascular disease, asthma, hyperthyroidism, receiving antihypertensive, antidepressants and anti-anxiety drugs and sensitivity to lidocaine, patients are excluded. One hundred patients requiring dental procedures are divided randomly into two groups of intervention and control. Inferior alveolar nerve block is performed by injection cartridges and 15 minutes after the injection and then lip anesthesia, access cavity is prepared. For the intervention group 1.8 mL cartridges containing 20 mg lidocaine hydrochloride 2% with 12.5 micrograms epinephrine 1/80000 with brand name of persocaine made by Daroopaksh Manufacturing Co. will be injected. For patients in the control group, the same volume of lidocaine hydrochloride 2% (100 mg per 5 ml) made by daroopaksh Co. will be injected and number of cartridges are recorded. Patients sit on dental unit in the semi-supine position and after 20 minutes rest, the patient's left arm is parallel to the surface of the heart. In 3 times (before and 15 minutes after the injection of local anesthesia and 10 minutes after the end of surgery) blood pressure and heart rate are measured and recorded and the results are compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017040533235N1**

Registration date: **2017-07-15, 1396/04/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-15, 1396/04/24

Registrant information

Name

Amirhossein Pakravan

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mazandaran University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of evaluation of blood pressure and heart rate by injecting epinephrine containing and without epinephrone local anesthetia

Public title

Evaluation of blood pressure and heart rate by injecting epinephrine containing local anesthetia

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: age 18 to 45 years; referring for removal of permanent teeth. Exclusion criteria: cardiovascular disease; asthma; hyperthyroidism; receiving antihypertensive, antidepressants and anti-anxiety drugs; sensitivity to lidocaine

Age
From **17 years** old to **45 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Using table of random numbers, patients are randomly divided into two groups, age and gender-matched

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Vice Chancellor for Research and Technology,
Moallem square, Sari, Iran

City

Sari

Postal code

Approval date

2017-03-15, 1395/12/25

Ethics committee reference number

IR.MAZUMS.REC.95.2338

Health conditions studied

1

Description of health condition studied

Blood pressure

ICD-10 code

Z01.3

ICD-10 code description

Examination of blood pressure

2

Description of health condition studied

Heart beat

ICD-10 code

R00.8

ICD-10 code description

Abnormalities of heart beat

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

Before injection of anesthetic, 15 minutes after the injection of local anesthesia and 10 minutes after the end of surgery

Method of measurement

mmHg

2

Description

Diastolic blood pressure

Timepoint

Before injection of anesthetic, 15 minutes after the injection of local anesthesia and 10 minutes after the end of surgery

Method of measurement

mmHg

3

Description

Heart rate

Timepoint

Before injection of anesthetic, 15 minutes after the injection of local anesthesia and 10 minutes after the end of surgery

Method of measurement

Number per minute

Secondary outcomes

empty

Intervention groups

1

Description

For the intervention group 1.8 mL cartridges containing 20 mg lidocaine hydrochloride 2% with 12.5 micrograms epinephrine 1/80000 with brand name of persocaine made by Daroopaksh Manufacturing Co. will be injected.

Category

2**Description**

For patients in the control group, the same volume of lidocaine hydrochloride 2% (100 mg per 5 ml) made by daroopakhsh Co. will be injected

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Faculty of Dentistry of Mazandaran University of Medical Sciences

Full name of responsible person

Amirhossein Pakravan

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Faculty of Dentistry, Near Tooba Clinic, Khazar bou;evard, Sari

City

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Vice chancellor for research of Mazandaran University of Medical Sciences

Full name of responsible person

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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

Vice chancellor for research of Mazandaran University of Medical Sciences

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**

Mazandaran University of Medical Sciences

Full name of responsible person

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Assistant Professor

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Full name of responsible person

Shahryar Karami

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Student

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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