Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial of comparison of heart rate and blood pressure changes due to administration of anesthesia agent with and without vasoconstrictor in healthy subjects.

Protocol summary

Summary

Objectives: The aim of this study is the comparison of heart rate and blood pressure changes due to administration of local anesthetic agent with and without vasoconstrictor. Design: Randomized clinical trial. Setting and Conduct: We study 182 patients referring for extraction of Mandibular Molar teeth in dentistry clinic of Tabriz faculty of dentistry in the form of two equal groups. Patients will randomly be assigned into one of two groups. We use Lidocaine2%+1:80000 Epinephrine cartridge for one group and Mepivacaine 3% cartridge for the other group. Participants including major eligibility criteria: Patients referring for Mandibular teeth extraction at the age range of 25 to 50 years will enroll into the study. Patients with chronic usage of any drugs, history of any systemic disease and any allergy for Lidocaine, Mepivacaine and Adrenaline will be excluded. Intervention: After randomly assigning into two groups we use Lidocaine2%+1:80000 Epinephrine cartridge for one group and Mepivacaine 3% cartridge for the other group. Main outcome measures (variables): Systolic and Diastolic blood pressure and heart rate before and 15 minutes after tooth extraction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013011510935N2**
Registration date: **2013-03-09, 1391/12/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-03-09, 1391/12/19

Registrant information

Name

Mohammad Ali Ghavimi

Name of organization / entity

Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2012-09-21, 1391/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparison of heart rate and blood pressure changes due to administration of anesthesia agent with and without vasoconstrictor in healthy subjects.

Public title

Comparison of heart rate and blood pressure changes due to administration of local anesthetic agent with and without Vasoconstrictor.

Purpose

Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria: 1-Being at the age between 25-50 years; 2-Indication for Mandibular Molar teeth extraction. Exclusion criteria: 1-History of any systematic disease; 2-History of chronic usage of any drug in the past 6 months; 3-Any allergy to Lidocaine, Mepivacaine and Adrenaline.
Age
From **25 years** old to **50 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **182**
Randomization (investigator's opinion)
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 Tabriz University of medical sciences and health services
Street address
Central office of Tabriz university of medical sciences, Golgasht street, Azadi street.
City
Tabriz
Postal code
5165687386
Approval date
2013-01-24, 1391/11/05
Ethics committee reference number
91188

Health conditions studied

1

Description of health condition studied
Hypertension
ICD-10 code
I10
ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Pulse rate
Timepoint
15 minutes before intervention, 15 minutes after intervention
Method of measurement
Pulse rate per minute- Pulse oxymeter

2

Description
Blood Pressure
Timepoint
15 minutes before intervention, 15 minutes after intervention
Method of measurement
Milimeter Hg- Manometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 2% Lidocaine+ Epinephrine 1:800000, 3.6miligrams, 15 minutes before tooth extraction, Gingival injection
Category
Treatment - Drugs

2

Description
Control group: Meoivacaine 3%, 3.6 miligrams, 15 miutes before tooth extraction, Gingival injection
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dentistry clinic of Tabriz Dentistry faculty
Full name of responsible person
Dr.Mohammad Ali Ghavimi
Street address
Tabriz faculty of dentistry, Golgasht street, Daneshgah street
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for reserach, Tabriz university of medical sciences
Full name of responsible person
Seyed Kazem Shakouri
Street address
Golgasht street, Daneshgah street
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for reserach, Tabriz 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
Tabriz faculty of Dentistry, Tabriz university of medical sciences
Full name of responsible person
Dr. Mohammad Ali Ghavimi
Position
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Person responsible for scientific inquiries

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Associate Professor
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Person responsible for updating data

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Web page address

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