

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

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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

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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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Associate Professor

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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