

# 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)

#### Phone

+98 41 1334 6147

#### Email address

ghmd@irimc.org

### 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**

DDS Oral and Maxillofacial surgery

**Other areas of specialty/work****Street address**

Maxillofacial surgery ward, Faculty of dentistry, Tabriz university of medical sciences, Daneshgah street

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Tabriz

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Ghavimim@Gmail.com

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Tabriz faculty of dentistry

**Full name of responsible person**

Dr. Javad Yazdani

**Position**

Associate Professor

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Maxillofacial surgery ward, Tabriz faculty of dentistry, Golgasht street, Daneshgah street

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yazdaniij@tbzmed.ac.ir

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## Person responsible for updating data

**Contact****Name of organization / entity**

Tabriz faculty of dentistry

**Full name of responsible person**

Afshar Abdolkarimi

**Position**

Student of dentistry

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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*