

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of effect of three local anesthesia including lidocaine 2% epinephrine 1/80000, prilocaine 3% flypressin 0/03%, plain mepivacaine 3% on blood pressure in hypertensive patients before tooth extraction

Protocol summary

Summary

Recommendation for use of epinephrine in dental local anesthesia is not for agreement in hypertensive patients. However several study allow its use with regard to maximum doses. In this study, patients that referred for mandibular tooth extraction and are hypertensive known case and their pre injection blood pressure is lower than 159/94 mmHg, are selected. They are randomly divided to three groups with 20 members. Group 1 persocaine solution (lidocaine 2% epinephrine 1/80000- darou pakhsh, Iran), group 2 dentanest (prilocaine 3% felypressin 0/03 IU- darou pakhsh , Iran) and group3 scandinibsa(plain mepivacaine3%- inibsa, Spania). Solution volume is determined two cateridges (3/6 ml) (maximum dose for epinephrine equally with 0/04 mgr). blood pressure is recorded in three time with pulse oximetry. Time 1 (before injection) that is 5 minute after sit down and resting on dental unit. Immediately after injection (time 2) and 5 minutes later (time 3) blood pressure is recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013061013621N1**

Registration date: **2013-06-23, 1392/04/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-06-23, 1392/04/02

Registrant information

Name

Seyed Hamed Jalalian Hashemi

Name of organization / entity

Zahedan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 54 1241 4004

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hamedjh59@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research and Technology Assistance of Zahedan University of Medical Science

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2013-07-23, 1392/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of three local anesthesia including lidocaine 2% epinephrine 1/80000, prilocaine 3% flypressin 0/03%, plain mepivacaine 3% on blood pressure in hypertensive patients before tooth extraction

Public title

Effects of different anesthetic agents in patients with controlled hypertension

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients who need inferior alveolar nerve block injection to extraction teeth; patients with

high blood pressure but under control and below 94/159 mmHg. Exclusion criteria: cardiovascular disease: unstable angina, myocardial infarction before 6 months, 6 months following cerebrovascular accident, CABG under 6 months, uncontrolled cardiac arrhythmias, decompensated congestive heart disease; untreated hyperthyroid, uncontrolled diabetes mellitus; sulfate-sensitive asthma, real allergies to sulfites; pregnant and lactating women.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Zahedan University of Medical Science

Street address

University of Medical Science, Dr Hesabi square

City

Zahedan

Postal code

9817699693

Approval date

2013-06-21, 1392/03/31

Ethics committee reference number

92-2092

Health conditions studied**1****Description of health condition studied**

Blood pressure of patients

ICD-10 code

Z01.3

ICD-10 code description

Examination of blood pressure

Primary outcomes**1****Description**

Blood pressure

Timepoint

3 times: 5 min before injection, immediately after injection and 5 min after injection

Method of measurement

Blood pressure is measured in millimeters of mercury with a pulse oximeter

Secondary outcomes

empty

Intervention groups**1****Description**

Two anesthetic cartridges containing lidocaine 2% epinephrine 1/80000

Category

Treatment - Drugs

2**Description**

Two anesthetic cartridges containing prilocaine 3% flypressin 0/03%

Category

Treatment - Drugs

3**Description**

Two anesthetic cartridges containing mepivacaine 3%

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Department of surgery - Zahedan Dental School

Full name of responsible person

Shamsoodin Rigi

Street address

Dental School, Azadegan Street

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research and Technology Assistance of Zahedan
University of Medical Science

Full name of responsible person

Dr Hamid Reza Mahmood Zade Sagheb

Street address

University of Medical Science, Dr Hesabi square

City

Zahedan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research and Technology Assistance of Zahedan
University of Medical Science

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**

Zahedan University of Medical Science

Full name of responsible person

Shamsoodin Rigi

Position

Dental student

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

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Specialist in Oral and Maxillofacial Surgery

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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