Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Email address

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

Dental School, Azadegan street

City

Zahedan

Postal code

9817699693

Phone

+98 54 1244 1814

Fax

Email

shams554@ymail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Science

Full name of responsible person

Dr Seyed Hamed Jalalian

Position

Specialist in Oral and Maxillofacial Surgery

Other areas of specialty/work

Street address

Dental School, Azadegan street

City

Zahedan

Postal code

9817699693

Phone

+98 54 1244 1814

Fax

+98 54 1241 4003

Email

hamedjh59@yahoo.co.in

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Zahedan University of Medical Science

Full name of responsible person

Dr Seyed Hamed Jalalian

Position

Specialist in Oral and Maxillofacial Surgery

Other areas of specialty/work

Street address

Dental School, Azadegan street

City

Zahedan

Postal code

9817699693

Phone

+98 54 1244 1814

Fax

Email

hamedjh59@yahoo.co.in

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