

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Hemodynamic changes (heart rate, blood pressure and oxygen saturation) comparing mepivacaine Hcl 3% with prilocaine 3%+ felypressin in controlled hypertensive patients after infra-alveolar block.

Protocol summary

2020-09-03, 1399/06/13

Study aim

Assessing hemodynamic changes (heart rate, blood pressure and oxygen saturation) comparing mepivacaine Hcl 3% with prilocaine 3%+ felypressin in controlled hypertensive patients after infra-alveolar block.

Design

Clinical trial, with parallel groups, double-blind, randomized, phase 2 on 32 patients. Excel software rand function was used for randomization.

Settings and conduct

Patients referred to the surgical ward of Shiraz Dental School are selected at random. The drugs are coded as A and B without the researcher's awareness and randomly selected by the researcher.

Participants/Inclusion and exclusion criteria

Patients with hypertension who are controlled with antihypertensive drugs.

Intervention groups

Patients with hypertension are divided into two groups and as anesthesia drugs that have the least cardiovascular changes are used as anesthesia.

Main outcome variables

Changes in pulse, blood pressure, blood oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200707048045N1**

Registration date: **2020-09-03, 1399/06/13**

Registration timing: **retrospective**

Last update: **2020-09-03, 1399/06/13**

Update count: **0**

Registration date

Registrant information

Name

Ahmad Homayoun

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3228 4031

Email address

ahmad.homayoun9@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-22, 1399/04/02

Expected recruitment end date

2020-08-15, 1399/05/25

Actual recruitment start date

2020-06-22, 1399/04/02

Actual recruitment end date

2020-07-26, 1399/05/05

Trial completion date

2020-07-31, 1399/05/10

Scientific title

Hemodynamic changes (heart rate, blood pressure and oxygen saturation) comparing mepivacaine Hcl 3% with prilocaine 3%+ felypressin in controlled hypertensive patients after infra-alveolar block.

Public title

Vital sign changes in use of prilocaine and mepivacaine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with controlled hypertension who are willing to cooperate

Exclusion criteria:
Patients with a history of drug allergy, a history of asthma, nasal polyps, bronchospasm or angioedema, heart failure or liver failure, pregnancy, patients with idiopathic or congenital methemoglobinemia, patients with bleeding disorders, patients taking anticoagulant drugs failure to sign a written consent

Age
From **30 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **32**
Actual sample size reached: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
The drugs are coded into two groups A and B by the assistant and then the table of random numbers is used as code A of even numbers and code B of odd numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
The drugs are coded by the assistant without the researcher's knowledge and the patient is aware of participating in the study but does not know which of the two drugs is used.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

No 111, 7th Abrishami Alley

City

Shiraz

Province

Fars

Postal code

7147768518

Approval date

2020-06-21, 1399/04/01

Ethics committee reference number

IR.SUMS.DENTAL.REC.1399.061

Health conditions studied

1

Description of health condition studied

controlled hypertensive patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Heart rate

Timepoint

Before intervention and 10 , 30 minute after

Method of measurement

Pulse oximeter

2

Description

Blood pressure

Timepoint

Before intervention and 10 , 30 minute after

Method of measurement

Blood pressure monitor

3

Description

Blood oxygen saturation

Timepoint

Before intervention and 10 , 30 minute after

Method of measurement

Pulse oximeter

Secondary outcomes

1

Description

Stress score

Timepoint

before and after intervention

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: 16 patients with injection of perilocain 3%+ felypressin daru pakhsh

Category

Treatment - Drugs

2**Description**

Intervention group: 16 patients with mepivacain hydrochlorid 3% eksir

Category

Treatment - Drugs

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

Shiraz Dentistry University

Full name of responsible person

Ehsan Aliabadi

Street address

Dentistry University, Ghoaaabad

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7195615878

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Ehsan Aliabadi

Street address

The central building of Shiraz University of Medical Sciences, in front of Palestine St, Zand St, Shiraz

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Email

info@sums.ac.ir

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

50

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Ahmad Homayoun

Position

Dentistry student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Questionnaire, consent form, and data form

When the data will become available and for how long

Access period starts 6 months after printing

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers who are certified by academic and scientific institutions.

From where data/document is obtainable

Shiraz School of Dentistry

What processes are involved for a request to access data/document

Contact Shiraz Dental School Research Unit

Comments