Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

Protocol summary

Study aim
Assessing hemodynamic changes (heart rate, blood pressure and oxygen saturation) comparing mepivacaine Hcl 3% with perilocaine 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
2020-09-03, 1399/06/13

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 perilocaine 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, Ghoaabad
City
Shiraz
Province
Fars
Postal code
7195615878
Phone
+98 71 3626 3193
Email
dental@sums.ac.ir

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
City
Shiraz
Province
Fars
Postal code
۷۱۳۴۸۱۴۳۳۶
Phone
+98 71 3230 5410
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 updating data

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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