Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

Comparison of the effect of oral captopril with sublingual captopril in lowering blood pressure in patients with acute high blood pressure

Protocol summary

Study aim

Comparison of the effect of oral captopril with sublingual captopril on blood pressure of patients referred to hospital emergency room

Design

A clinical trial with a control group with a three-way blind phase three parallel group on 138 patients, rand function of Excel software will be used for randomization.

Settings and conduct

Randomization is done through variable blocking, and for the purpose of three-way blinding and without informing the randomizer, the drug and placebo are placed in an envelope with a code, and after measuring the blood pressure of the primary subjects, the drug and placebo are prescribed to the patient. In the group prescribed oral captopril 25 mg of Elixir Pharmaceutical Company, in order to blind the patient, simultaneous sublingual placebo was prescribed, and in the group prescribed sublingual captopril 25 mg of Elixir Pharmaceutical Company and placebo were administered orally at the same time.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with systolic blood pressure above 160 or diastolic blood pressure above 100 referring to the FAST (outpatient) emergency department of Khatam al-Anbia Hospital in 1401 Exclusion criteria: 1) Patients who need blood pressure injection treatment and hospitalization. 2) Patients who have used blood pressure pills an hour before the visit. 3) Patients who have a history of kidney problems. 4) Patients who are over 65 years old. 5) Patients who are younger than 18 years old 6) Patients with end organ damage 7) Pregnancy 8) Decreased level of consciousness

Intervention groups

After randomization, patients are divided into two groups and receive either oral captopril or sublingual captopril.

Main outcome variables

Blood pressure ؛ blood pressure assessment time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220516054869N2**
Registration date: **2022-08-08, 1401/05/17**
Registration timing: **prospective**

Last update: **2022-08-08, 1401/05/17**
Update count: **0**

Registration date

2022-08-08, 1401/05/17

Registrant information

Name

ali abdolrazaghnejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3323 2890

Email address

ali.abdolrazaghnejad@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of oral captopril with sublingual captopril in lowering blood pressure in patients with acute high blood pressure

Public title
Comparison of the effect of oral captopril with sublingual captopril in lowering blood pressure in patients with acute high blood pressure

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with systolic blood pressure above 160 or diastolic blood pressure above 100 referred to the FAST (outpatient) emergency department of Khatam Al-Anbia Hospital in 1401

Exclusion criteria:
Patients who need blood pressure injection treatment and hospitalization Patients who have used blood pressure pills an hour before the visit Patients who have a history of kidney problems Patients with end organ damage Pregnancy Decreased level of consciousness

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **138**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation of patients to two groups is done by permuted block stratified randomization method designed with Random allocation software. In this way, first, eligible referring patients are classified according to age and gender in the order of entry. Then they are assigned to the desired group based on blocks of 4 (consisting of two groups A and B and two repetitions for each) randomly selected from among all the possible states of permutations. In order to hide the random allocation, envelopes will be used in the package.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this research, the triple-blind method is used. The patients will receive both forms of administration (sublingual and oral) with drugs and placebo and will be blinded to being in the intervention or control group. The data collector measures the desired outcomes and does not know which group the patient is in. The data analyst compares two groups coded A and B and is blinded to the control and intervention groups. .

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences

Street address
Dr. Hasabi Square - Zahedan University of Medical Sciences

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
43463 - 98167

Approval date
2022-07-24, 1401/05/02

Ethics committee reference number
IR.ZAUMS.REC.1401.151

Health conditions studied

1

Description of health condition studied
Acute hypertension

ICD-10 code
I10

ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Decreased blood pressure by more than 10 mm Hg

Timepoint
30, 10 and 60 minutes

Method of measurement
alpk2 300v mercury pressure gauge

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Sublingual captopril of Exir

pharmaceutical company 25 mg once after entering the study

Category
Treatment - Drugs

2

Description
Control group: Oral captopril 25 mg of Exir pharmaceutical company is prescribed to the patient after entering the study.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emergency department of Khatam al-Anbia Hospital, Zahedan

Full name of responsible person
Ali Abdolrazaghnejad

Street address
Khatam Square - Khatam Al Anbia Hospital

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9815733169

Phone
+98 54 3322 3003

Email
ali.abdorazzagh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
Normohammad Bakhshani

Street address
Pardis square - University of Medical Sciences - Research Vice-Chancellor

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9815733169

Phone
+98 54 3337 2117

Email
dr.bakhshani35@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Zahedan University of Medical Sciences

Proportion provided by this source
100

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
Zahedan University of Medical Sciences

Full name of responsible person
Ali Abdolrazaghnejad

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

Street address
Khatam Square - Khatam Al Anbia Hospital - Department of Emergency Medicine

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9815733169

Phone
+98 54 3322 3003

Email
ali.abdorazzagh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
Ali Abdolrazaghnejad

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

Street address
Khatam Square - Khatam Al Anbia Hospital - Department of Emergency Medicine

City
Zahedan

Province
Sistan-va-Balouchestan
Postal code
9815733169
Phone
+98 54 3322 3003
Email
ali.abdorazzagh@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Ali Abdolrazaghnejad
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Khatam Square - Khatam Al Anbia Hospital - Department of Emergency Medicine
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9815733169
Phone
+98 54 3322 3003
Email
ali.abdorazzagh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
The access period starts 12 months after the results are published
To whom data/document is available
Seas of documents will be available for researchers working in academic and scientific institutions
Under which criteria data/document could be used
For medical purposes, pharmaceutical companies can receive data analysis after sending a request.
From where data/document is obtainable
Applicants should write to the following postal address. ali.abdorazzagh@gamil.com
What processes are involved for a request to access data/document
After sending the request to the said postal address, as well as stating the purpose of accessing the data and documents, the applicant will receive the documents within a period of 12 weeks, if there is no conflict with the codes of medical ethics.
Comments