

# 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**

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**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**

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**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**

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

Zahedan University of Medical Sciences

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Associate professor

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**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**