

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of oral captopril in comparison with alprazolam and oral captopril in controlling blood pressure in patients with urgent hypertension.

Protocol summary

Study aim

Comparison of the effect of oral captopril in comparison with alprazolam and oral captopril in controlling blood pressure in patients with urgent hypertension

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 94 patients. Random allocation software is used for randomization.

Settings and conduct

The present study is a double-blind randomized parallel clinical trial. This study will be performed on patients with urgent hypertension referred to the emergency department of Imam Hossein Hospital in Shahroud. After ten minutes of rest after admission to the emergency department, blood pressure will be taken. After obtaining informed consent, the patient who meets the inclusion criteria will be placed in the control and intervention group based on the random allocation in the numbered envelopes. The patient's blood pressure is then retaken and recorded. In the intervention group, captopril 50 mg, alprazolam 0.5 mg, and control group captopril 50 mg and folic acid tablets are administered orally and only once for patients. Patients will be asleep and resting in bed during the study. Patients' blood pressure in both groups is taken with a mercury sphygmomanometer at 90, 60, 30, and 120 minutes after drug administration. In this study, patients and blood pressure assessors will be unaware of the type of drug prescribed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: systolic blood pressure above 180 or diastolic above 110, age group 18-80 years, ability to understand and sign informed consent, insensitivity to captopril or alprazolam

Intervention groups

In the control group, the main drug captopril will be given 50 mg orally and vitamin B, and in the intervention group, captopril 50 mg along with alprazolam 0.5 mg will

be given orally.

Main outcome variables

Systolic and diastolic blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220423054624N1**

Registration date: **2022-05-25, 1401/03/04**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-25, 1401/03/04**

Update count: **0**

Registration date

2022-05-25, 1401/03/04

Registrant information

Name

Maryam Sahba

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 5054

Email address

gity.shb@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of oral captopril in comparison with alprazolam and oral captopril in controlling blood pressure in patients with urgent hypertension.

Public title

Efficacy of Alprazolam on blood pressure control

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Systolic blood pressure over 180 or Diastolic blood pressure over 110 age between 18-80 years old Ability to understand and sign the conscientious informed consent No previous Allergy to Captopril or Alprazolam

Exclusion criteria:

Left Acute Heart Failure Chronic Renal Failure Cardiovascular disease History of stroke History of myocardial infraction Taking other Benzodiazepines in the last week Taking Muscle Relaxant drugs such as Baclofen Taking anti-anxiety drugs from other group such as Buspirone or Zolpidem Pregnant and Lactating women Occurring an emergency situation which indicates prescribing other Antihypertensive drug based on the Doctor's diagnosis Patients who have more than 15 mmHg difference in blood pressure between arms .

AgeFrom **18 years** old to **80 years** old**Gender**

Both

Phase

2

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **94****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients are randomly divided into two groups of 47 using random allocation software. An envelope will be prepared according to the number of samples, the code of each treatment group will be placed in the envelope, and each patient will be assigned an envelope in which the treatment group is written.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant: The use of captopril tablets with Folic acid tablets in one group and the use of captopril tablets and alprazolam tablets in another group that the patient is not aware of based on the same color, and shape, and through the use of drugs. Statistical Analyzer: The

treatment groups will be provided to the statistical analyzer using the code for analysis.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahroud University of Medical Sciences

Street address

Room 409, third floor , medical school , Shahroud University of Medical sciences and Health Services, Hafte-Tir Square ,Tehran avenue , Shahroud, Semnan, Iran

City

Shahroud

Province

Semnan

Postal code

3614773943

Approval date

2022-04-17, 1401/01/28

Ethics committee reference number

IR.SHMU.REC.1401.022

Health conditions studied**1****Description of health condition studied**

Essential (primary) hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes**1****Description**

Systolic and diastolic blood pressure

Timepoint

checking blood pressure at the beginning of the study and then at 30 ,60 , 90 and 120 minutes after the intervention.

Method of measurement

using a clinical mercury manometer device for monitoring the blood pressure in a standardized manner in which patient is lying down.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, patients' blood pressure will be taken and recorded before the drug is administered lying down and the standard method using a mercury sphygmomanometer. Patients are then given a 50 mg captopril tablet and a 0.5 mg alprazolam tablet orally. The drug is prescribed only once at the beginning of the study. The patient will be lying on the bed during the study. In order to check the blood pressure of patients, at 30, 60, 90 and 120 minutes after drug administration (4 times in total), patients' blood pressure is taken and recorded with a mercury sphygmomanometer. Due to the fact that the occurrence of drug side effects is one of the consequences, at 30, 60, 90 and 120 minutes after drug administration, the patient is monitored and the occurrence of side effects is evaluated.

Category

Treatment - Drugs

2

Description

Control group: In the control group, patients' blood pressure will be taken and recorded before the drug is prescribed and the standard method will be taken using a mercury sphygmomanometer. Patients are then given a 50 mg captopril tablet with one folic acid tablet orally. The drug is prescribed only once at the beginning of the study. The patient will be lying on the bed during the study. In order to evaluate the blood pressure status of patients in the control group, in 30, 60, 90 and 120 minutes after drug administration (4 times in total), patients' blood pressure is taken and recorded with a mercury sphygmomanometer. Also, at 30, 60, 90 and 120 minutes after drug administration, the patient is monitored and the occurrence of complications is evaluated.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein hospital

Full name of responsible person

Dr. Mohammad Reza Khorsand Kemachali

Street address

Emergency department, Imam Hossein Hospital,
Imam Hossein Square , Shahroud , Iran

City

Shahroud

Province

Semnan

Postal code

3614773947

Phone

+98 23 3239 5054

Email

a.noyani@shmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr Mohammad Hassan Emamian

Street address

Research Deputy, second floor, Medical school,
University of Medical Science , Hafte-Tir square ,
Tehran avenue, Shahroud, Semnan, Iran

City

Shahroud

Province

Semnan

Postal code

3614773943

Phone

+98 23 3239 5009

Email

a.noyani@shmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

DR. Mohammadreza khorsand Kemachali

Position

Supervisor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Room 409, Third floor , Medical School, Shahroud
University of Medical Science and Health Services,
Hafte Tir Square, Shahroud ,Iran

City

Shahroud

Province

Semnan

Postal code

3614773943

Phone

+98 23 3239 5054

Email

dr_khorsandmd@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr.Mohammadreza Khorsand Kemachali

Position

Supervisor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Room 409, Third floor , Medical School, Shahroud
University of Medical Science and Health Services,
Hafte Tir Square, Shahroud ,Iran

City

Shahroud

Province

Semnan

Postal code

3614773943

Phone

+98 23 3239 5054

Email

dr_khorsandmd@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mostafa Enayatrad

Position

Statistical advisor

Latest degree

Master

Other areas of specialty/work

Epidemiology

Street address

Room 409, Third floor , Medical School, Shahroud
University of Medical Science and Health Services,
Hafte Tir Square, Shahroud ,Iran

City

Shahroud

Province

Semnan

Postal code

3614773943

Phone

+98 23 3239 5054

Email

Mostafaenayatrad@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 collected data will be shared after being unidentified
and analysed

When the data will become available and for how long

By the end of 2023

To whom data/document is available

For all scholars

Under which criteria data/document could be used

For use in studies

From where data/document is obtainable

Emergency department of Imam Hossein Hospital in
Shahroud. Responsible person is Dr. Mohammad Reza
Khorsand. Postal Code 3614773943 Contact number
09126733459 Imam Hassan Hospital in Shahroud.
Emergency department

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

dr.mohammadreza khorsand Email
dr_khorsandmd@yahoo.com

Comments