Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 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 .
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
2
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target 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.mohhamadreza khorsand Email dr_khorsandmd@yahoo.com

Comments