# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

21 Jul 2026

## Comparison and Evaluation of the Effect of Oral Captopril and Carvedilol in Patients with Hypertension Urgency.

### Protocol summary

**Study aim**
Comparison of efficacy and patient satisfaction with oral captopril and oral carvedilol in Urgency hypertension.

**Design**
The clinical trial has 2 intervention groups in parallel, two-way blind, randomization with block randomization method on 70 samples.

**Settings and conduct**
A clinical trial will be performed on patients with urgency hypertension who meet the inclusion criteria in khatam hospital.Variables will be collected in predetermined minutes by a health care provider who will not know the type of medicine.The patient does not know the type of medicine.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria 1.Refer to the hospital emergency room with symptoms of blood pressure equal to or greater than 160/90 millimeter of mercury in patients with hypertension or blood pressure equal to or greater than 180/110 millimeter of mercury in patients with new onset of the disease in the age range of 18 to 65 years Exclusion criteria 1.Acute chest pain 2.Pulmonary edema 3.Patients who need intravenous drugs to control blood pressure 4.Loss of consciousness and Cerebrovascular events failure 5.Acute renal 6.Pregnancy 7.Papillary edema

**Intervention groups**
Patients will be divided into two groups: A (taking captopril 25 mg orally) and group B (taking carodilol 6.25 mg orally).

**Main outcome variables**
Systolic, diastolic blood pressure, heart rate, mean blood pressure, satisfaction rate

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20200723048182N1**
Registration date: **2020-08-03, 1399/05/13**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-03, 1399/05/13**
Update count: **0**

**Registration date**
2020-08-03, 1399/05/13

**Registrant information**

**Name**
sina sarchahi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 51 4333 5515

**Email address**
dr.sinasrc@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-09-21, 1398/06/30

**Expected recruitment end date**
2020-09-20, 1399/06/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparison and Evaluation of the Effect of Oral Captopril and Carvedilol in Patients with Hypertension Urgency.

**Public title**
Effect of Captopril and Carvedilol in Hypertension

Urgency.

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Refer to the hospital emergency department with symptoms of blood pressure equal to or greater than 160/90 mmHg in patients with hypertension or blood pressure equal to or greater than 180/110 mmHg in patients with new onset of the disease in the age range of 18 to 65 years. Obtaining written consent from patients. Complete the file and information contained in the questionnaire form.

**Exclusion criteria:**

Failure to obtain written consent from patients Defects in the file and information contained in the questionnaire form Patients with acute chest pain Bradycardia History of heart block or sick sinus syndrome Irreversible heart failure Pulmonary edema Aortic dissection Patients who need intravenous drugs to control blood pressure or require high doses of ACEIs and ARBs (captopril> 50 mg / d, enalapril> 10 mg / d, lisinopril> 5 mg / d, losartan> 50 mg / d, valsartan > 80 mg / d). Loss of consciousness Seizure Cerebrovascular accidents (ischemia or bleeding) Acute or chronic renal failure Previous history of pheochromocytoma History of bilateral renal artery stenosis Pregnancy Hypertension after surgery Diastolic blood pressure above 120 History of allergies to captopril and carvedilol and allergies to penicillin and sulfonamides. Asthma or other bronchospasm diseases Existence of cardiogenic shock Severe liver failure Papillary edema Anuria

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

If the inclusion criteria are met and blood pressure does not decrease after 20 minutes of bed rest, patients will be divided into two groups with Random block method: A (taking captopril 25 mg orally) and group B (taking carodilol 6.25 mg orally).Randomization will be done by Random Allocation software.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

If the inclusion criteria are met and blood pressure does not decrease after 20 minutes ,after randomization by block method and placing patients in two groups A and B.In order to eliminate the bias caused by the patient's awareness and the health care provider (who is responsible for giving the capsule to the patient and measuring and recording information from the beginning of the study) to the type of treatment received and its possible impact on the results,The study will be conducted in double blind study, therefore Captopril and carvedilol tablets are placed in the same capsules so that the patient and the health care provider are not informed about the type of medication received.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Islamic Azad University of semnan

**Street address**

Islamic Azad University of semnan Complex, Daneshgahi Town, semnan

**City**

semnan

**Province**

Semnan

**Postal code**

37111-35131

**Approval date**

2019-08-03, 1398/05/12

**Ethics committee reference number**

IR.IAU.SEMNAN.REC.1398.021

## Health conditions studied

### 1

**Description of health condition studied**

Hypertension

**ICD-10 code**

I10

**ICD-10 code description**

Essential (primary) hypertension

## Primary outcomes

### 1

**Description**

Systolic blood pressure

**Timepoint**

In 10, 20, 30, 45, 60, 90, 120 and 180 minutes after drug administration

**Method of measurement**

With a hand pressure gauge and with a scale of

millimeters of mercury

**2**

**Description**
Diastolic blood pressure
**Timepoint**
In 10, 20, 30, 45, 60, 90, 120 and 180 minutes after drug administration
**Method of measurement**
With a hand pressure gauge and with a scale of millimeters of mercury

**3**

**Description**
Mean blood pressure
**Timepoint**
In 10, 20, 30, 45, 60, 90, 120 and 180 minutes after drug administration
**Method of measurement**
After measuring systolic and diastolic blood pressure its measured with the sum of twice the diastolic blood pressure and the systolic blood pressure divided by three ((2DBP + SBP)/3) will be calculated.

**4**

**Description**
Heart rate
**Timepoint**
In 10, 20, 30, 45, 60, 90, 120 and 180 minutes after drug administration
**Method of measurement**
By counting the number of radial pulses

## Secondary outcomes

**1**

**Description**
Satisfaction rate
**Timepoint**
At intervals and ends of measurements
**Method of measurement**
questionnaire

**2**

**Description**
Drug side effects
**Timepoint**
At intervals and ends of measurements
**Method of measurement**
questionnaire

## Intervention groups

**1**

**Description**
Intervention group: Taking captopril 25 mg orally and in a single dose
**Category**
Treatment - Drugs

**2**

**Description**
Intervention group: Taking carodilol 6.25 mg orally and in a single dose
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Khatam al-Anbia Hospital
**Full name of responsible person**
Hossein Haratipour
**Street address**
Khatam al-Anbia Hospital, Daneshgah Blv
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Islamic Azad University
**Full name of responsible person**
Behrouz Yahyaei
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**Email**
dr.sinasrc@gmail.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor**

**organization/entity?**
No
**Title of funding source**
Sina Sarchahi
**Proportion provided by this source**
100
**Public or private sector**
Private
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Persons

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Islamic Azad University
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Nasrin Razavianzadeh
**Position**
Associate professor
**Latest degree**
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## Person responsible for updating data

**Contact**
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Sina Sarchahi
**Position**
Medical intern
**Latest degree**
A Level or less
**Other areas of specialty/work**
Medical Education
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36148-71151
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dr.sinasrc@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be 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