Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
City
شاهرود
Province
Semnan
Postal code
36148-71151
Phone
+98 23 3233 9661
Fax
+98 23 3233 1876
Email
khatam@shahrood.ac.ir
Web page address
http://khatam.iau-shahrood.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Behrouz Yahyaei
Street address
Khatam al-anbia Hospital, Daneshgah Blv
City
Shahroud
Province
Semnan
Postal code
36148-71151
Phone
+98 23 3233 9661
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
Full name of responsible person
Nasrin Razavianzadeh
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
Khatam al-Anbia Hospital, Daneshgah Blv
City
Sharoud
Province
Semnan
Postal code
36148-71151
Phone
+98 23 3233 9661
Email
nasrinrazavianzadeh@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
nasrin razavianzadeh
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
Khatam al-Anbia Hospital, Daneshgahi Blv
City
Shahroud
Province
Semnan
Postal code
36148-71151
Phone
+98 23 3233 9661
Email
nasrinrazavianzadeh@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Sina Sarchahi
Position
Medical intern
Latest degree
A Level or less
Other areas of specialty/work
Medical Education
Street address
Khatam al-Anbia Hospital, Daneshgahi Blv
City
Shahroud
Province
Semnan
Postal code
36148-71151
Phone
+98 23 3233 9661
Email
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