Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison and evaluation of the effectiveness of oral captopril and oral hydrochlorothiazide in the treatment of urgency hypertensive patients

Protocol summary

Study aim
Comparison and evaluation of the effectiveness of oral captopril and oral hydrochlorothiazide in the treatment of urgency hypertensive patients

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

Settings and conduct
This study will be performed as a double-blind clinical trial (patient and interventionist) in patients with urgency hypertension who will be randomly divided into two equal groups of 35 patients in Khatam Al-Anbia Hospital in Shahroud.

Participants/Inclusion and exclusion criteria
Admission requirements: Refer to the hospital emergency department of patients with known hypertension with a blood pressure of 160/90 mm Hg or more and patients with the New-onset Hpertension with blood pressure of 180/110 mm Hg or more without organ damage (urgency blood pressure) in patients aged 18 to 65 years Exclusion criteria: 1. Patients who need intravenous drugs to control blood pressure 2. Patients with myocardial infarction presenting with acute chest pain 3. Patients with severe renal or hepatic insufficiency 4. Papillary edema 5. Pulmonary edema 6. Decreased level of consciousness and cerebrovascular accidents 7. Pregnant patients

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

Main outcome variables
systolic blood pressure, diastolic blood pressure, mean blood pressure, heart rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200722048172N1**
Registration date: **2020-08-10, 1399/05/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-10, 1399/05/20**
Update count: **0**

Registration date
2020-08-10, 1399/05/20

Registrant information

Name
MOHAMMAD AMIN QAREHKHANI

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 17 3572 6109

Email address
maq1372@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 effectiveness of oral captopril and oral hydrochlorothiazide in the treatment of urgency hypertensive patients

Public title

Comparison and evaluation of the effectiveness of oral captopril and oral hydrochlorothiazide in the treatment of urgency hypertensive patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with known hypertension with a blood pressure of 160/90 mm Hg or more and patients with the new-onset sever hypertention with a blood pressure of 180/110 mm Hg or more without organ damage (urgency) will be included in the study if satisfied. Patients between the ages of 18 and 65 will be included in the study.

Exclusion criteria:

Patients who need intravenous drugs to control their blood pressure or other blood pressure medications for different reasons. Patients who need high dose of ACEIs or ARBs (> 50 mg/d Captopril, > 10 mg/d Enalapril, > 5 g/dLisinopril, > 50 mg/d Losartan, > 80 mg/d Valsartan),to control their blood pressure. Patients with myocardial infarction presenting with acute chest pain. Patients with severe renal or hepatic failure,anuria, papillaryedema, pulmonary edema, loss of consciousness, seizure,aortic dissection, or bilateral renal artery stenosis; pregnantpatients, patients with a history of overt allergy or angioedemawith ACEIs, Allergy to penicillins and sulfonamides.

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 rest, after randomization of the block and placing patients in two groups A and B in order to eliminate the bias caused by patient awareness and health care (which task The capsule is given to the patient and the measurements and information are recorded from the beginning of the study) depending on the type of treatment received and its possible effect on the results, the study will be performed blindly, so captopril and hydrochlorothiazide tablets in exactly the same capsules They are placed so that the patient and the health care provider are not informed about the type of medicine received.

Blinding (investigator's opinion)

Double blinded

Blinding description

If the inclusion criteria are met and after 20 minutes of rest and taking 2 equal blood presses 5 minutes apart, patients are randomly divided into two equal groups by block randomization. The drug is then given by a special clinical caregiver who is not aware of the type of drug to the study participant who is also not an absolute drug to be swallowed with water in the standard way and then in 10, 20, 30, 45, 60, 90, 120, 180 minutes After administration of the drug, systolic, diastolic blood pressure and heart rate in the sitting physical position will be taken by the same clinical caregiver.

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, Semnan Branch

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.1398.022

Health conditions studied

1

Description of health condition studied

Urgency 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, 180 minutes after drug administration

Method of measurement
With a hand pressure guage and with ascale of millimeters of mercury

2

Description
Diastolic Blood Pressure
Timepoint
In 10, 20, 30, 45, 60, 90, 120, 180 minutes after drug administration
Method of measurement
With a hand pressure guage and with ascale of millimeters of mercury

3

Description
Mean Blood Pressure
Timepoint
10, 20, 30, 45, 60, 90, 120, 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 systolic blood pressure divided by three (3 / (2DBP + SBP)) will be calculated.

4

Description
Heart Rate
Timepoint
10, 20, 30, 45, 60, 90, 120, 180 minutes after drug administration
Method of measurement
It will be obtained by counting the number of pulses per minute.

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:Take hydrochlorothiazide 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., University Blvd
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Shahroud
Province
Semnan
Postal code
3614871151
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., University Blvd
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3614871151
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Email

maq1372@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Mohammad Amin Qarehkhani

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

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Nasrin Nazavianzadeh

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohammad Amin Qarehkhani

Position

Medical Intern

Latest degree

A Level or less

Other areas of specialty/work

Cardiology

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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