

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Comparison of efficacy and patients satisfaction of sub lingual and oral captopril patients with hypertension

Protocol summary

Summary

The aim of this study is comparison of efficacy and patient satisfaction of oral and sub lingual captopril in hypertensive patient. This is double blind clinical trial study. Patients with systolic blood pressure ≥ 160 and diastolic blood pressure ≥ 100 mmgh will be included and acute cardiac ischemia; pulmonary edema; loss of consciousness; acute renal failure and pregnancy will be excluded. After explaining the objectives of the study and obtaining the informed consent, patients randomized to random block 4-way A and B are divided two treatment group. one group with oral captopril and the second group with sub lingual captopril 25 mg will be treated. Systolic blood pressure, diastolic blood pressure, heart rate and patient satisfaction are study out comes.

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Recruitment status

Recruitment complete

Funding source

Shahrood Islamic Azad University

Expected recruitment start date

2015-12-06, 1394/09/15

Expected recruitment end date

2016-04-03, 1395/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110924963N1**

Registration date: **2015-12-24, 1394/10/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-24, 1394/10/03

Registrant information

Name

Mania Armin

Name of organization / entity

Islamic Azad University Shahrood branch

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 0360

Scientific title

Comparison of efficacy and patients satisfaction of sub lingual and oral captopril patients with hypertension

Public title

Efficacy and patients Satisfaction of sub lingual and oral captopril in hypertensive patient

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion: blood pressure 160/100 and more than
exclusion: evidence of existence of acute ischemic heart disease; chest pain; dynamic change in EKG; heart failure; pulmonary edema; dissection of aorta; encephalopathy due to hypertension; seizure; loss of consciousness; cerebrovascular accident(ischemic , hemorrhagic); acute and chronic renal failure; history of pheochromocytoma; previous history of bilateral renal artery stenosis; pregnancy; hypertension after surgery; diastolic blood pressure >120 ; history of allergic reaction to captopril.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences, Hafte Tir Square, Shahroud

City

Shahroud

Postal code**Approval date**

2015-08-26, 1394/06/04

Ethics committee reference number

IR.SHMU.REC.1394.116

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

10,20,30,45,60,90,120 min after drug administration

Method of measurement

blood pressure cuff, mmhg

2**Description**

Diastolic Blood Pressure

Timepoint

10,20,30,45,60,90,120 min after drug administration

Method of measurement

blood pressure cuff, mmhg

3**Description**

Pulse rate

Timepoint

10,20,30,45,60,90,120 min after drug administration

Method of measurement

Per Min

4**Description**

Respiratory Rate

Timepoint

10,20,30,45,60,90,120 min after drug administration

Method of measurement

Per Min

Secondary outcomes**1****Description**

Vomiting

Timepoint

after 2 hours

Method of measurement

Questionnaire

2**Description**

Headache

Timepoint

after 2 hours

Method of measurement

Questionnaire

3**Description**

Nausea

Timepoint

after 2 hours

Method of measurement

Questionnaire

4**Description**

Muscular Cramp

Timepoint
after 2 hours
Method of measurement
Questionnaire

5

Description
cough
Timepoint
after 2 hours
Method of measurement
Questionnaire

6

Description
Cutaneous Rash
Timepoint
after 2 hours
Method of measurement
Questionnaire

Intervention groups

1

Description
Sub Lingual Captopril 25 mg, single dose
Category
Treatment - Drugs

2

Description
Oral Captopril, 25 mg, single dose
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Dr Nasrin Razavian Zadeh
Street address
City
Shahrod

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahrood Islamic Azad University
Full name of responsible person
Dr Majid Salami
Street address

Tehran Blvd, Shahrood Islamic Azad University
City
Shahrood
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahrood Islamic Azad University
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shahrood Islamic Azad University
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Person responsible for updating data

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00

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty