

# 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  $\geq 160$  and diastolic blood pressure  $\geq 100$ 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.

#### 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

##### Email address

mania-armin@iau-shahrood.ac.ir

##### 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

##### 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  
**Full name of responsible person**  
Mania Armin  
**Position**  
Medical Student  
**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

**Contact**  
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Internist, Shahrood Islamic Azad University  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Islamic Azad University  
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Dr Mehdi Musavi  
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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*