

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of Pentoxifylline and Captopril combination therapy versus Captopril mono therapy on blood pressure control in patients with hypertension: Randomized clinical trial

Protocol summary

Study aim

Evaluation of blood pressure in Pentoxifylline and Captopril group
Evaluation of blood pressure in Captopril and placebo group
Compare blood pressure in Pentoxifylline and Captopril group with Captopril and placebo group

Design

Randomised controlled clinical trial, single blinded

Settings and conduct

This study is randomized clinical trial, which will be done on total of 60 consented patients older than 18 years with diagnosis of stage 1 hypertension who attended the Shahid Madani clinic of Tabriz University of Medical Science and have indication of Captopril therapy according to standard treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of primary stage 1 hypertension according to JNC-7 guideline
Informed consent of patient
Exclusion criteria: Moderate and severe renal failure, liver failure
Contraindications of Captopril and Pentoxifylline
Patients with secondary hypertension, pregnancy and lactation

Intervention groups

Patients in intervention group receive 400 mg extended release Pentoxifylline, 3 times a day plus 25 mg Captopril, 3 times a day orally for 2 months. Patients in control group receive 25 mg Captopril and placebo 3 times a day orally for 2 months.

Main outcome variables

comparison of blood pressure level before beginning of study and two months after study, between two under study groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111206008307N31**

Registration date: **2019-04-27, 1398/02/07**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-27, 1398/02/07**

Update count: **0**

Registration date

2019-04-27, 1398/02/07

Registrant information

Name

Taher Entezari-Maleki

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 4709

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tentezarimaleki@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-08, 1398/01/19

Expected recruitment end date

2019-06-09, 1398/03/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Pentoxifylline and Captopril combination

therapy versus Captopril mono therapy on blood pressure control in patients with hypertension:Randomized clinical trial	
Public title	Effect of Pentoxifylline and Captopril combination therapy on blood pressure control in patients with hypertension
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Diagnosis of primary stage 1 hypertension according to JNC-7 guideline Informed consent of patient
Exclusion criteria:	Moderate and severe renal failure liver failure Contraindications of Captopril and Pentoxifylline Patients with secondary hypertension Pregnancy and lactation
Age	From 18 years old to 80 years old
Gender	Both
Phase	2-3
Groups that have been masked	No information
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	Randomization will be performed by permuted block randomization with a block size of 2 and an allocation ratio of 1:1 in two groups of intervention and control group.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of Ardabil University of Medical Sciences
Street address	University street, Ardabil
City	Ardabil
Province	Ardabil

Postal code	۵۶۱۸۹۸۵۹۹۱
Approval date	2018-11-11, 1397/08/20
Ethics committee reference number	IR.ARUMS.REC.1397.129
Health conditions studied	
<u>1</u>	
Description of health condition studied	Primary hypertension
ICD-10 code	I10
ICD-10 code description	Essential (primary) hypertension
Primary outcomes	
<u>1</u>	
Description	Blood pressure
Timepoint	Measurement of blood pressure before intervention and two months after intervention
Method of measurement	Mercury Manometer
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
Description	Intervention group: Patients in this group receive 400 mg extended release Pentoxifylline , 3 times a day plus 25 mg Captopril, 3 times a day orally for 2 months.All of the drugs used in this dtudy are generic and they do not have specific brand.
Category	Treatment - Drugs
<u>2</u>	
Description	Control group: Patients in this group receive 25 mg Captopril and placebo 3 times a day orally for 2 months.
Category	N/A
Recruitment centers	
<u>1</u>	
Recruitment center	
Name of recruitment center	Shahid Madani Medical & Training Hospital

Full name of responsible person

Dr. Taher Entezari-Maleki

Street address

Daneshgah Street, Shahid Madani Hospital

City

Tabriz

Province

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-

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afsaris@tbzmed.ac.ir

Web page address

https://madanihosp.tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

Dr. Shahab Bohlooli

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s.bohlooli@pharmacy.arums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ardabil University of Medical Sciences

Proportion provided by this source

50

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

2

Sponsor**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

آقای دکتر ابوالقاسم جویبان

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Daneshgah Street

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

50

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Taher Entezari Maleki

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All of the data of an article can be published after making patients unrecognized

When the data will become available and for how long

After publishing of article until 6 months after publishing of the results

To whom data/document is available

Data will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers that request data will be permitted only to doing analysis according to ethics for scientific aims

From where data/document is obtainable

Applicants can receive data by sending an E-mail to address of tentezari@gmail.com and get response from Dr. Taher Entezari Maleki

What processes are involved for a request to access data/document

After contacting with corresponding author(Dr.Taher Entezari Maleki), data will be sent to Tabriz Shahid Madani hospital ethics committee and after receiving permission data will be send to applicants

Comments