

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Pharmacist led self-monitoring of blood pressure versus conventional management in patients with hypertension

Protocol summary

Study aim

Evaluating efficacy of pharmacist based self-monitoring of blood pressure in patients with hypertension in comparison with conventional method by physician.

Design

Randomized, not blinded, parallel group, controlled clinical trial between September 2016 and June 2017

Settings and conduct

The present study was carried out at cardiovascular clinic of Shahid-Madani hospital. The sample size was 150 people who visited within 6 months.

Participants/Inclusion and exclusion criteria

Patients with hypertension and over 18 years of age who signed the consent form were enrolled in the study. Patients with secondary hypertension, pregnant women, nursing mothers, and patients who cannot measure his/her blood pressure were excluded from the study.

Intervention groups

In intervention group, patients were measured their blood pressure by using digital blood pressure machine which were calibrated by the pressure gauge of the clinic. All patients were trained by a clinical pharmacist to measure their blood pressure and adjust their medications based on the protocol. The method used was that if the blood pressure of patients without any background problem was higher than 90/140 mmHg or in patients with background problems such as diabetes and ischemic heart disease was higher than 80/130 mmHg, they increase the dosage of their drugs. If they had beta-blockers in their treatment regimen, they increase its dose to control the pacing of the heart to a range of 70-60 ppm. In the case of a chest pain, they were allowed to use sublingual TNG up to 3 doses in 5 minutes intervals to improve the symptoms. If their systolic blood pressure was higher than 180 mm Hg, they should use sublingual captopril. In control group, conventional method by cardiologist was used to manage patients' blood pressure

Main outcome variables

Comparing blood pressure of patients between intervention and control groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111206008307N29**

Registration date: **2018-08-08, 1397/05/17**

Registration timing: **retrospective**

Last update: **2018-08-08, 1397/05/17**

Update count: **0**

Registration date

2018-08-08, 1397/05/17

Registrant information

Name

Taher Entezari-Maleki

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-09-21, 1395/06/31

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

2016-09-21, 1395/06/31

Actual recruitment end date

2017-06-14, 1396/03/24
Trial completion date
empty

Scientific title
Pharmacist led self-monitoring of blood pressure versus conventional management in patients with hypertension

Public title
Pharmacist led self-monitoring of blood pressure versus conventional management

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
outpatients with primary hypertension patients with 18 years old and over consented patients
Exclusion criteria:
secondary hypertension pregnancy nursing mothers liver failure kidney failure heart failure anti-hypertensive drugs contraindications patients who cannot measure his/her blood pressure blind people lack of required qualifications for satisfaction

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **150**
Actual sample size reached: **126**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization was done using computer systematic randomization by an independent person.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Tabriz University of Medical Science

Street address

Research and Technology Deputy, Tabriz University

of Medical Science, Golgasht Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766

Approval date

2016-08-11, 1395/05/21

Ethics committee reference number

TBZMED.REC.1394.1135

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

blood pressure

Timepoint

before intervention and 4,8 , 12 weeks after intervention

Method of measurement

sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients were measured their blood pressure by using digital blood pressure machine which were calibrated by the pressure gauge of the clinic. All patients were trained by a clinical pharmacist to measure their blood pressure and adjust their medications based on the protocol. The method used was that if the blood pressure of patients without any background problem was higher than 90/140 mmHg or in patients with background problems such as diabetes and ischemic heart disease was higher than 80/130 mmHg, they increase the dosage of their drugs. If they had beta-blockers in their treatment regimen, they increase its dose to control the pacing of the heart to a range of 70-60 ppm. In the case of a chest pain, they were allowed to use sublingual TNG up to 3 doses in 5 minutes intervals to improve the symptoms. If their systolic blood pressure was higher than 180 mm Hg, they should use sublingual captopril.

Category

Treatment - Other

2

Description

Control group: Conventional method was used to control blood pressure by a cardiologist.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics of Shahid Madani Hospital

Full name of responsible person

Taher Entezari-Maleki

Street address

Clininc of Shahid Madani Hospital,Golgasht Street,Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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

100

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/ Clinical pharmacist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Position

Assistant professor/ Clinical pharmacist

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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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

No - There is not 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