

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

The effect of citalopram on blood pressure and quality of life in patients with resistant hypertension

Protocol summary

Study aim

To evaluate the effect of citalopram (20 mg/day) on blood pressure and quality of life in patients with resistant hypertension.

Design

A parallel-group, randomized, open-label controlled trial with 60 patients (30 per group). Randomization by ChatGPT-generated sequence with fixed seed; sequential allocation.

Settings and conduct

This pilot study will be conducted at the clinic of Shahid Madani Hospital, Tabriz. Eligible patients with resistant hypertension will be enrolled consecutively. They will be allocated to intervention (n=30) or control (n=30) groups. The intervention group will receive citalopram 20 mg/day added to their existing triple antihypertensive therapy for 2 months. The control group will continue their triple antihypertensive therapy alone. Blood pressure will be measured at baseline, 1 month, and 2 months. Quality of life (SF-12) and psychological status (DASS-21) will be assessed at baseline and at 2 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with resistant hypertension referred to the clinic. Non-inclusion criteria: · Lack of consent or follow-up possibility · Secondary hypertension · Contraindication or hypersensitivity to citalopram/SSRIs · Pregnancy or breastfeeding · Concurrent serotonergic drugs or drug interactions · Severe renal or advanced liver disease

Intervention groups

Intervention group: Citalopram 20 mg/day added to their existing triple antihypertensive therapy for 2 months. Blood pressure measured at baseline, 1, and 2 months. Quality of life assessed at baseline and 2 months. Control group: Continues existing triple antihypertensive therapy alone for 2 months. Blood pressure and quality of life assessed at the same time points.

Main outcome variables

Change in systolic and diastolic blood pressure from

baseline to 2 months; Change in quality of life score (SF-12) from baseline to 2 months.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260719070255N1**

Registration date: **2026-08-06, 1405/05/15**

Registration timing: **registered_while_recruiting**

Last update: **2026-08-06, 1405/05/15**

Update count: **0**

Registration date

2026-08-06, 1405/05/15

Registrant information

Name

Midia Rashidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3338 1217

Email address

midiarashidi00@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-23, 1405/05/01

Expected recruitment end date

2027-03-20, 1405/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of citalopram on blood pressure and quality of life in patients with resistant hypertension

Public title

Effect of citalopram on resistant hypertension

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with resistant hypertension who refer to the clinic.

Exclusion criteria:

Lack of informed consent or inability to comply with follow-up visits
Diagnosed secondary hypertension
History of hypersensitivity or contraindication to citalopram or other SSRIs
Pregnancy or breastfeeding
Concurrent use of serotonergic drugs or other medications with potential interaction with citalopram
Severe renal impairment or advanced liver disease

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients will be randomly allocated to intervention and control groups in a 1:1 ratio using a randomization sequence generated by an artificial intelligence model (ChatGPT). The AI-generated random sequence will be produced with a fixed seed to ensure reproducibility. The allocation will be performed sequentially at the time of patient enrollment using the generated random list.

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2026-06-10, 1405/03/20

Ethics committee reference number

IR.TBZMED.REC.1405.153

Health conditions studied**1****Description of health condition studied**

Resistant hypertension

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Percentage of patients with resistant hypertension

Timepoint

At baseline, at 1 month, and at 2 months

Method of measurement

Aneroid sphygmomanometer

2**Description**

Change in quality of life score

Timepoint

Baseline, and at 2 months

Method of measurement

12-Item Short-Form Health Survey

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

Change in psychological status score

Timepoint

Baseline, and at the end of 2 months

Method of measurement

Depression, Anxiety and Stress Scale - 21 Items

Intervention groups**1**

Description

Intervention group: Patients in this group will receive citalopram 20 mg/day orally, added to their existing triple antihypertensive therapy. The treatment will continue for 2 months. Blood pressure will be measured at baseline, 1 month, and 2 months. Quality of life (SF-12) and psychological status (DASS-21) will be assessed at baseline and at the end of 2 months.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group will continue their existing triple antihypertensive therapy alone, without any additional medication, for 2 months. Blood pressure will be measured at baseline, 1 month, and 2 months. Quality of life (SF-12) and psychological status (DASS-21) will be assessed at baseline and at the end of 2 months.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani hospital

Full name of responsible person

Dr Hosein Namdar

Street address

Shahid Madani Hospital, Imam Khomeini St.,
Daneshgah St.

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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

Midia Rashidi

Position

Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Hosein Namdar

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology
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Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Hosein Namdar
Position
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Latest degree
Subspecialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

This is a pilot study with a small sample size (60 patients). Individual participant data (IPD) will not be shared due to the pilot nature of the study and confidentiality considerations.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable