Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 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

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Iran (Islamic Republic of)

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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

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Position
Associate professor
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Cardiology

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Person responsible for updating data

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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