

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jun 2026

Study of Evaluation of the therapeutic effects of Hab Shabyar on Intraocular pressure in patients with open-angle glaucoma: A double-blind clinical trial

Protocol summary

Summary

This study is a double-blind randomized controlled clinical trial with two groups. In this study, patients with open-angle glaucoma with IOP 11-21 mm Hg will be included in the trial and patients who have angle-closure glaucoma, Crohn's and Colitis Disease, hemorrhoids, use of systemic drugs to interfere with the IOP and pregnant women will be excluded from the study. In this study, fifty patients with open-angle glaucoma (IOP between 11-22 mm Hg) will be referred by an ophthalmologist or by group researchers and will be invited with using the announcement and providing sufficient information. After obtaining written informed consent, eligible patients will be enrolled and randomly assigned to two groups. Random numbers table will be used for sample randomization and patients will be divided into two groups: interventional group (25 persons) and control group (25 persons). Control group will be received placebo and intervention group will be received shabyar pills for two months (once daily). In addition, two groups will be received conventional therapy (timolol every 12 hours). In fact, the interventional group (with shabyar) and the control group (placebo) will be given placebo or shabyar for one month and after a month IOP will be measured by Goldmann tonometer. Then, two groups will be received placebo or shabyar for a month again. After this time, patients' intraocular pressure will be measured and recorded again for two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052828127N1**

Registration date: **2016-12-08, 1395/09/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-08, 1395/09/18

Registrant information

Name

Ebrahim khalil Banihabib

Name of organization / entity

Tabriz University of Medical-School of Traditional Medicine

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 9527

Email address

banihabib.e@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor, Tabriz University of Medical Sciences

Expected recruitment start date

2016-06-19, 1395/03/30

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of Evaluation of the therapeutic effects of Hab Shabyar on Intraocular pressure in patients with open-angle glaucoma: A double-blind clinical trial

Public title

Evaluation of the therapeutic effects of Iranian Traditional Medicine (Hab Shabyar) in patients with open-angle glaucoma: A double-blind clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 20-70 years; patients with open-angle glaucoma with IOP 11-21 mm Hg; patients with Informed consent. Exclusion criteria: patients that who have angle-closure glaucoma; Crohn's and Colitis Disease; hemorrhoids; use of systemic drugs to interfere with the IOP and pregnant women.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

patients were randomly enrolled. Random method in survey is numbers table and patients will divide to two groups .

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz

City

Tabriz

Postal code

5165665912

Approval date

2016-04-11, 1395/01/23

Ethics committee reference number

IR.TBZMED.REC.1395.9

Health conditions studied

1

Description of health condition studied

open-angle glaucoma

ICD-10 code

H40.1

ICD-10 code description

Primary open-angle glaucoma

Primary outcomes

1

Description

Intraocular pressure

Timepoint

Before the intervention, one month after and two months after intervention

Method of measurement

IOP measurement with Goldmann tonometer

Secondary outcomes

1

Description

side effects

Timepoint

One month and two months after intervention

Method of measurement

questionnaire

Intervention groups

1

Description

Control group: will be received placebo daily

Category

Placebo

2

Description

Intervention group: will be received shabyar pills daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baharan Clinic of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Ali Mostafaei

Street address

Baharan Clinic, Azadi Street, Tabriz
City
Tabriz

banihabib.e@umsu.ac.ir;
dr_banihabib1390@yahoo.com
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research (VCR) of Tabriz
University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

International Relations Office, No 2 Central Building,
Tabriz University of Medical Sciences, University
Street, Tabriz

City

Tabriz

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

Yes

Title of funding source

Vice Chancellor for Research (VCR) of Tabriz University of
Medical Sciences

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**

School of Traditional Medicine, Tabriz University of
Medical Sciences

Full name of responsible person

Ebrahim khalil Banihabib

Position

MD PhD Student of Traditional Medicine

Other areas of specialty/work**Street address**

School of Traditional Medicine, Tabriz University of
Medical Sciences, Azadi Street, University Street,
Tabriz,

City

Tabriz

Postal code**Phone**

+98 41 3337 9527

Fax**Email**

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Ali Mostafaei

Position

Associate Professor

Other areas of specialty/work**Street address**

Baharan Clinic, Azadi Street, Tabriz

City

Tabriz

Postal code**Phone**

+98 41 3334 3245

Fax**Email**

alimostafaie@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

School of Traditional Medicine

Full name of responsible person

Ebrahim khalil Banihabib

Position

MD PhD Student of Traditional Medicine

Other areas of specialty/work**Street address**

School of Traditional Medicine, Tabriz University of
Medical Sciences, Azadi Street, Tabriz

City

Tabriz

Postal code**Phone**

+98 41 3337 9527

Fax**Email**

banihabib.e@umsu.ac.ir;

dr_banihabib1390@yahoo.com

Web page address

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