

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The explanation of the causes of high blood pressure and its therapies in Persian medicine and the effect of Lemongrass herbal product in primary blood pressure control

Protocol summary

Study aim

Explain the causes of hypertension and its treatment based on persian medicine and determine the effectiveness of the product of lemon balm on primary hypertension.

Design

This study is a double-blind, Crossover, randomized clinical trial. The sample size is 24 patients in each group , which according to the cross-sectional study, the total results of 48 patients in each group will be examined. Patients are divided into two groups of medication and placebo.

Settings and conduct

Patients are randomly assigned to receive four weeks of medication and four weeks of placebo. The washout period is considered two weeks. In this double blind study, the researcher and the patient will not be informed about how to receive capsules in the intervention and control groups until the end of the study.

Participants/Inclusion and exclusion criteria

Major inclusion criteria: Men and women aged 30-75 years, with a systolic blood pressure greater than or equal to 140 and a diastolic blood pressure greater than or equal to 90 mmHg, are treated with a blood pressure medication (one to three drugs based on the protocol). Major exclusion criteria: presence of blood pressure greater than or equal to 110/180 mm Hg, history of secondary hypertension, end-organ damage symptoms 6 months before the start of the study, history of hypo or hyperthyroidism.

Intervention groups

Adding a Melitropic capsule to the medication regimen in the intervention group, control group: placebo capsule

Main outcome variables

Change in blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170820035796N2**

Registration date: **2019-01-08, 1397/10/18**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-08, 1397/10/18**

Update count: **0**

Registration date

2019-01-08, 1397/10/18

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2277 0208

Email address

z.shekarriz@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The explanation of the causes of high blood pressure and its therapies in Persian medicine and the effect of Lemongrass herbal product in primary blood pressure control

Public title

Evaluation of the effect of lemon balm plant on primary blood pressure control

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Men and women 30-75 years old Systolic blood pressure greater than or equal to 140, and diastolic blood pressure greater than or equal to 90 mmHg being treated with blood pressure medication (one to three drugs based on the protocol), but the patient's blood pressure is uncontrolled At least one month has elapsed since the onset of drug use Have informed consent to participate in the study.

Exclusion criteria:

Blood pressure equal to or greater than 110/180 at the start of the study or during intervention History of secondary hypertension Major symptoms of major organ damage (such as renal failure, congestive heart failure, myocardial infarction, or cerebrovascular accidents) During the 6 months before the study The presence of any type of cardiac arrhythmia (such as second- or third-degree blocks) Symptomatic valvular disease Liver dysfunction Type 1 and type 2 diabetic patients with impaired renal and liver function to the extent that clinically significant (ie more than 1.5 times the maximum normal creatinine and alanine aminotransferase more than 3 times the normal maximum) Low platelet count More than 100,000 per microliter of blood History of treated or untreated malignancies Potassium greater than 1.5 or less than 3.5 mg / L in the first visit History of hypothyroidism or hyperthyroidism Pregnancy and lactation The presence of any medical or surgical disorder that could interfere with the study.

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are categorized into two groups A and B by block randomization method. In the first four weeks, group A receives drug and group B placebo and after the washout period, group A receives placebo and group B

drug. Unit of randomization is individual and samples are allocated by the software "random allocation". The samples are grouped in 12 blocks of 4.

Blinding (investigator's opinion)

Double blinded

Blinding description

melitropic and placebo capsules with quite the same shape and color and weight will be produced and packaged in quite the same and will be one color and one shape. After the washout period, melitropic and placebo will be changed for each patient. A code will be randomly assigned to each box with the help of software. The expert will give it to the patient accidentally and without knowledge of the type of medicine. Thus the nature of each code will be unclear until the results are analyzed. The investigator, expert and patient will not be aware of the code in the container.

Placebo

Used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mazandaran University of Medical Sciences

Street address

Deputy of Research and Technology Mazandaran University of Medical Sciences, Moalem Ave., Moalem Square

City

Sari

Province

Mazandaran

Postal code

48168-95474

Approval date

2018-09-26, 1397/07/04

Ethics committee reference number

IR.MAZUMS.REC.1397.156

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

In baseline and 5 times follow up measurement every 2 weeks

Method of measurement

Sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Miliotropic capsule containing 400 mg of lemon balm daily three times a day for 4 weeks

Category

Treatment - Drugs

2

Description

Control group: The capsule contains 400 mg of lactose daily three times a day for 4 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tooba clinic

Full name of responsible person

Seyde Sedighe Yousefi

Street address

Tooba clinic, Khazar Blvd., Khazar Square

City

Sari

Province

Mazandaran

Postal code

48168-95474

Phone

+98 11 3324 4893

Fax

+98 11 3324 4894

Email

s.yousefi@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

Street address

Deputy of Research and Technology Mazandaran University of Medical Sciences, Moalem Ave., Moalem Square

City

Sari

Province

Mazandaran

Postal code

861-48175

Phone

+98 11 3325 7230

Email

m.saeedi@mazums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Seyde Sedighe Yousefi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Traditional and Complementary Medicine Research Centre, Khazar Blvd., Khazar square

City

Sari

Province

Mazandaran

Postal code

48168-95475

Phone

+98 11 3324 4893

Fax

+98 11 3324 4894

Email

z.shekarriz@mazums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Seyde Sedighe Yousefi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Traditional and Complementary Medicine Research
Centre, Khazar Blvd., Khazar square

City

Sari

Province

Mazandaran

Postal code

48168-95475

Phone

+98 11 3324 4893

Fax

+98 11 3324 4894

Email

s.yousefi@mazums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Zahra Shekarriz

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

Traditional and Complementary Medicine Research
Centre, Khazar Blvd., Khazar square

City

Sari

Province

Mazandaran

Postal code

48168-95475

Phone

+98 11 3324 4893

Fax

+98 11 3324 4894

Email

z.shekarriz@mazums.ac.ir

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

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

Statistical Analysis Plan

No - There is not 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