Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Studying the efficacy of Thymus vulgaris extract in controlling Metabolic syndrome components in patients referred to Baqiyatallah hospital

Protocol summary

Study aim
Studying the efficacy of Thymus vulgaris extract in controlling dyslipidemia,systolic and diastolic hypertension,insulin resistance and abdominal obesity in Metabolic syndrome patients.

Design
This study is a randomized, placebo-controlled, double-blind, phase 3 clinical trial with two parallel groups. Two hundred Metabolic syndrome patients who have eligibility criteria will be selected and randomely divided into case and placebo groups using computerized randomization and followed for twelve weeks .

Settings and conduct
This trial will be done in Heart Clinic of Baqiyatallah hospital. The Metabolic syndrome patients who have the eligibility criteria will selected and after taking history, physical exams and required laboratory test , drug package(Thyme extract or placebo capsule) will be given and followed for twelve weeks and then all exams and tests will be repeated.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 20 to 65 years old Metabolic syndrome patients who have more than three of five conditions according to "American Heart Association/the National Heart, Lung, and Blood Institute (AHA/NHLBI) criteria". Exclusion criteria: History of cardiac, hepatic, kidney, thyroid and psychiatry disease; Drug history of antihypertensive, antihyperlipidemic, hepatotoxic and antidiabetic drugs ; Pregnancy and lactation ; Hypersensitivity to thyme;

Intervention groups
Treatment group: Thymus vulgaris extract capsule 500 milligram twice a day for twelve weeks. Control group: Placebo Capsule with the same shape,size and color of original drug twice a day for twelve weeks.

Main outcome variables
Waist circumference ; Fasting blood glucose ; Systolic and diastolic blood pressure ; Serum lipid profile ;

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190815044533N1**
Registration date: **2020-01-04, 1398/10/14**
Registration timing: **prospective**

Last update: **2020-01-04, 1398/10/14**
Update count: **0**

Registration date
2020-01-04, 1398/10/14

Registrant information
Name
Hamid Babahosseini
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
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Email address
hbabahosseini@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-01-21, 1398/11/01
Expected recruitment end date
2020-08-22, 1399/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Studying the efficacy of Thymus vulgaris extract in controlling Metabolic syndrome components in patients referred to Baqiyatallah hospital

Public title

Efficacy of Thyme in Metabolic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having at least 3 of the following 5 conditions for diagnosing Metabolic syndrome according to "American Heart Association the National Heart, Lung, and Blood Institute (NHLBI)AHA/NHLBI criteria" including: 1)Elevated fasting glucose: Equal to or greater than 100 mg/dL or use of medication for hyperglycemia 2)Elevated waist circumference: Men – greater than 102 cm and Women – greater than 88 cm 3)Elevated triglycerides: Equal to or greater than 150 mg/dL 4)Reduced HDL cholesterol:Men – Less than 40 mg/dL and Women – Less than 50 mg/dL 5) Elevated blood pressure: Equal to or greater than 130/85 mm Hg or use of medication for hypertension

Exclusion criteria:

History of coronary artery disease, previous angioplasty or CABG, congenital heart disease and heart failure Drug history of anti hypertension drugs or other drugs which increase or decrease the blood pressure History of liver disease , hepatitis , cirrhosis, alcohol abuse, using hepatotoxic drugs within 6 months ago Kidney disease (such as CKD , nephrotic and nephritic syndrome , AKI، kidney artery stenosis) Thyroid dysfunction and using levothyroxine Using anti hyperlipidemic agents Using anti diabetic agents and insulin Pregnancy and lactation Psychiatric disorders which impaired regular drug using History of active cancer or treatment with chemotherapic drugs Hypersensitivity to thyme and its ingredients History of bariatrics surgery

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Each drug package (including 100 boxs of Thymus vulgaris extract capsule and 100 boxs of placebo capsule which are absolutely same in all characters except effective material and packed in same boxs) previously superscribed with an equivalent 4-digit code using computerized randomization. The computerized randomization will done using " Random allocation software 2.0 ® " for Windows 7 ®. We will produce a simple randomized list for a sample size of 200 subjects into two groups of cases with equal size. The output code is numeric with the length of four digit. The software will printed the random four-digit codes that are matched with case or placebo group. These codes will be saved in a secret file in computer. Nobody could understand the type of drug from its shape, box or code except the analyzer at the end of trial using the secret file. Each patient who enter to trial will be given a drug box and the 4-digit code will register in his/her folder.

Blinding (investigator's opinion)

Double blinded

Blinding description

A drug box with a four-digit code will allocate to each patients.these box are exactly same. the placebo and extract capsules are also same in shape, size and color. Nobody could understand the type of drug from its shape, box or code. These codes are randomly matched with placebo or case groups by the computerized randomization. All patients , the practitioner, assessor who collect informations in both visits will be blind. Only the analyzer will have access the group of patients at the end of trial.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baqiyatallah University of Medical Sciences

Street address

Molla Sadra street. - Baqiyatallah University of Medical Sciences - Ethics in research committee

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2019-12-10, 1398/09/19

Ethics committee reference number

IR.BMSU.REC.1398.302

Health conditions studied

1

Description of health condition studied

Metabolic syndrome

ICD-10 code
E88.81
ICD-10 code description
Metabolic syndrome

2

Description of health condition studied
Hyperlipidemia
ICD-10 code
E78.2
ICD-10 code description
Mixed hyperlipidemia

3

Description of health condition studied
Overweight and obesity
ICD-10 code
E66
ICD-10 code description
Overweight and obesity

4

Description of health condition studied
هایپرتنشن اولیه
ICD-10 code
I10
ICD-10 code description
Essential (primary) hypertension

5

Description of health condition studied
Type 2 diabetes mellitus with hyperglycemia
ICD-10 code
E11.65
ICD-10 code description
Type 2 diabetes mellitus with hyperglycemia

Primary outcomes

1

Description
Systolic and Diastolic arterial pressure
Timepoint
Beginning of study and then 12 weeks later
Method of measurement
With a "Calibrated handheld pressure gauge"

2

Description
Serum Fasting Blood Glucose
Timepoint
Beginning of study and then 12 weeks later
Method of measurement
Laboratory measurement of Serum sample Fasting blood glucose

3

Description
Waist circumference
Timepoint
Beginning of study and then 12 weeks later
Method of measurement
Measurement of waist circumference using a Tape measure in the level of umbilicus

4

Description
Serum Triglyceride level
Timepoint
Beginning of study and then 12 weeks later
Method of measurement
Laboratory measurement of Serum sample Teriglyceride level

5

Description
Serum high dense lipoprotein (HDL) level
Timepoint
Beginning of study and then 12 weeks later
Method of measurement
Laboratory measurement of Serum sample High dense lipoprotein (HDL)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Thymus vulgaris extract capsule 500 mg twice aday for 12 weeks which will be donate by Barij essence drug company .
Category
Treatment - Drugs

2

Description
Control group: Placebo capsule (which is same in shape ، color , size and smell with orginal drug) twice aday for for 12 weeks which will be donate by Barij essence drug company .
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
The heart clinic of Baqiyatallah hospital.
Full name of responsible person

Dr. Hamid Babahosseini

Street address

Polyclinic of Baqiyatallah hospital. - Molla Sadra Str. - Vanak Sq.

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Web page address

https://baq.bmsu.ac.ir/Portal/Home/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr. Hamidreza Taghipour

Street address

Baqiyatallah medical university. - Mollasarda str. - Vanak Sq.

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Phone

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Email

hospital.research2@gmail.com

Web page address

https://research.bmsu.ac.ir/portal/home

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah 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

Tehran University of Medical Sciences

Full name of responsible person

Hamid Babahosseini

Position

as researcher

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hamid Babahosseini

Position

as researcher

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

as researcher

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+98 21 4466 9612
Email
hbabahosseini@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Personal informations are not published. We will publish the information after statistical analysis.
When the data will become available and for how long
The patients file information and data could be accessed just in a short periods of time during statistical analysis presumably 2 months in summer 2020.
To whom data/document is available
The data analyzer during statistical analysis and the practiotioner during entering the information could have access to information .
Under which criteria data/document could be used
The information will be accessed by analyzer in a short period of time with a 4-digit code without any name. the information will used just with informed consent of patients and just after statistical analysis.
From where data/document is obtainable
The informations will file in archive administration of Baqiyatallah hospital.
What processes are involved for a request to access data/document
In order to reach the patients Folders which are archived , person should refer to protective administration for recieving allowance letter .
Comments