Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of the efficacy of Thymoxymel with 10% thyme and Thymoxymel with 1.5 g thyme and 3 g thyme on weight loss in overweight people

Protocol summary

Study aim

Determine the efficacy of Thymoxymel with 10% thyme and Thymoxymel with 1.5 g thyme and 3 g thyme on weight loss in overweight people

Design

108 people who have been admitted to the study, who had been previously visited by the doctor, are divided into three groups of 36 members by randomly assigned random numbers.Blocked randomization is intended to ensure that exactly the same number of participants participates in consecutive but equal intervals, into three groups.The size of each block in this study is 36 We assign a number between 1 and 6 to each of the three permutations then we generate 36 random numbers in range 1 through 6 by RANDBETWEEN in Excel

Settings and conduct

108 patients who referred to university clinics who had studied in the study group were divided into 3 groups and To the first group, a normal oxymel with thyme flavor twice everyday 10 cc (as a placebo)To the second group, oxymel with 1.5 grams of thyme , twice everyday 10 cc,To the third group, oxymel with 3 grams of thyme , twice everyday 10 cc,The medication should be given to all three groups for a period of three months at monthly intervals.The shape and taste of all three types of medication are the same.During the study, all people, including doctors, patients, and the person in charge of delivery of the drug, will not be aware of the drug used.

Participants/Inclusion and exclusion criteria

inclusion criterea : Body mass index (BMI) above 25 kg / m Conscious Consent to Participate in the Study Waist to hip ratio index (WHR) in men1 and women 0.9 Not taking any medications in the past month exclusion criterea: pregnancy lactation alcohol use diabetes melitus thymus allergy reaction history acute or chronic liver disease cancer hypo or hyper thyroidism renal failuer Gastroesophageal reflux Unwillingness of the patient to continue participating in the plan for any reason

Intervention groups

the first group, a normal oxymel with thyme flavor twice everyday 10 cc (as a placebo)To the second group, oxymel with 1.5 grams of thyme , twice everyday 10 cc,To the third group, oxymel with 3 grams of thyme , twice everyday 10 cc

Main outcome variables

Weight check in the first and the end of study , Abdominal circumference to hip circumference ratio check in the first and the end of study, BMI check in the first and the end of study , FBS check in the first and the end of study , Liver enzyme check in the first and the end of study, Lipid profile check in the first and the end of study

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171220037976N1**
Registration date: **2018-04-21, 1397/02/01**
Registration timing: **prospective**

Last update: **2018-04-21, 1397/02/01**
Update count: **0**

Registration date

2018-04-21, 1397/02/01

Registrant information

Name

Jafar Abolghasemy nezhad shirazi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3639 5768

Email address

shirazij@sums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-06-22, 1397/04/01
Expected recruitment end date
2018-09-22, 1397/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the efficacy of Thymoxymel with 10% thyme and Thymoxymel with 1.5 g thyme and 3 g thyme on weight loss in overweight people

Public title
The study of the effect of Thyme oxymel on over weight
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Body mass index (BMI) above 25 kg / m Conscious Consent to Participate in the Study Waist to hip ratio index (WHR) in men1 and women 0.9 Not taking any medications in the past month
Exclusion criteria:
pregnancy lactation alcohol use diabetes melitus thymus allergy reaction history acute or chronic liver disease cancer hypo or hyper thyroidism renal failuer Gastroesophageal reflux Unwillingness of the patient to continue participating in the plan for any reason
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **108**
Randomization (investigator's opinion)
Randomized
Randomization description
108 people who have been admitted to the study, who had been previously visited by the doctor, are divided into three groups of 36 members by randomly assigned random numbers.Blocked randomization is intended to ensure that exactly the same number of participants participates in consecutive but equal intervals, into three groups.The size of each block in this study is 36 We assign a number between 1 and 6 to each of the three permutations then we generate 36 random numbers in range 1 through 6 by RANDBETWEEN in Excel
Blinding (investigator's opinion)
Double blinded
Blinding description
To the first group, a normal oxymel with thyme flavor twice everyday 10 cc (as a placebo)To the second group, oxymel with 1.5 grams of thyme , twice everyday 10 cc,To the third group, oxymel with 3 grams of thyme , twice everyday 10 cc,The medication should be given to all three groups for a period of three months at monthly intervals.The shape and taste of all three types of medication are the same.During the study, all people, including doctors, patients, and the person in charge of delivery of the drug, will not be aware of the drug used.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
medical School, Zand Street,Imam Hossein Square,Shiraz
City
Shiraz
Province
Fars
Postal code
7134845794
Approval date
2017-11-06, 1396/08/15
Ethics committee reference number
IR.SUMS.MED.REC.1396.89

Health conditions studied

1

Description of health condition studied
obesity - over weight
ICD-10 code
E66.9
ICD-10 code description
Obesity, unspecified

Primary outcomes

1

Description

Body Mass Index

Timepoint

monthly

Method of measurement

From the division of weight into squared height

Secondary outcomes

1

Description

lipid profile study

Timepoint

At the start and end of study

Method of measurement

blood sampling

2

Description

liver enzyme study

Timepoint

At the start and end of study

Method of measurement

blood sampling

3

Description

abdominal to hip circumference ratio study

Timepoint

monthly

Method of measurement

by meter

4

Description

weight

Timepoint

monthly

Method of measurement

scale

Intervention groups

1

Description

Control group: oxymel with thyme flavore 10 cc twice daily

Category

Placebo

2

Description

Intervention group1: thyme oxymel with 1.5 gram thyme in 10 cc twice daily

Category

Treatment - Drugs

3

Description

Intervention group2: thyme oxymel with 3 gram thyme in 10 cc twice daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Martyr Clinic

Full name of responsible person

Jafar Abolghasemy

Street address

Namazi Square ,Shiraz

City

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Postal code

713485794

Phone

+98 71 3230 5645

Email

shirazij@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Basir Hashemi

Street address

Central Building of Shiraz University of Medical Sciences, Zand Avenue

City

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Jafar Abolghasemy Nezhad Shirazi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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jafar20200@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Majid Nimruzi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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School of Medicine, Zand Avenue, next to the Governor's Office,shiraz

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Jafar Abolghasemy nezhad shirazi

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

BMI- WHR- Average Fat Profiles Participants - Average liver Profile of Participants-Average age of participants - the number of men and women who participated in the study

When the data will become available and for how long

After doing the data analysis and printing the article

To whom data/document is available

All interested researchers

Under which criteria data/document could be used

To complete the same work and through obtaining permission via email or telephone

From where data/document is obtainable

By Dr. Jafar Abolghasemi on 09171130442 or at the

Faculty of Medicine of Shiraz, the Department of Traditional Medicine or email address jafar20200@yahoo.com

What processes are involved for a request to access data/document

Submission of the request will then be made within one week of the requested information

Comments