Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the Effect of Topical use of Chamomile oil and Dill oil on Abdominal Obesity and Comparison with Placebo Group_ A Randomized Clinical Trial

Protocol summary

Study aim
Determining the effect of topical application of chamomile and dill oil on abdominal obesity

Design
Randomized clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients, rand function of Excel software was used for randomization.

Settings and conduct
This study is conducted in the form of a double-blind randomized clinical trial among those who refer to Iranian medical treatment centers.

Participants/Inclusion and exclusion criteria
Main Inclusion Criteria: Women between the ages of 25 and 55 years with a waist circumference of >= 80 cm who have the necessary cooperation in taking the medicine and are not pregnant. Main Exclusion Criteria: Not using another topical drug that interferes with the effect of the studied drug Use other weight loss methods

Intervention groups
Intervention group: 6 weeks of the combination of chamomile oil and dill oil once a day in the amount of 2 cc per square meter (in such a way that the entire abdominal area except for the radius of 2 cm around the navel (10 cm square) is completely lubricated and with a thin layer of oil should be covered) without massaging the area. After using the oil, cover the area with a plastic cover and have 30 minutes of aerobic activity and the plastic cover is removed from the abdomen after the aerobic activity. Control group: topical use of placebo oil (sesame oil) according to the instructions of the intervention group

Main outcome variables
1- Abdominal circumference size 2- Abdominal subcutaneous fat thickness in three areas

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230902059321N1**
Registration date: **2023-10-18, 1402/07/26**
Registration timing: **retrospective**

Last update: **2023-10-18, 1402/07/26**
Update count: **0**

Registration date
2023-10-18, 1402/07/26

Registrant information

Name
Maryam Bashiri

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-22, 1401/03/01

Expected recruitment end date
2022-12-22, 1401/10/01

Actual recruitment start date
2022-05-22, 1401/03/01

Actual recruitment end date
2022-11-06, 1401/08/15

Trial completion date
empty

Scientific title
Evaluation of the Effect of Topical use of Chamomile oil and Dill oil on Abdominal Obesity and Comparison with Placebo Group_ A Randomized Clinical Trial

Public title
Effect of Topical use of Chamomile oil and Dill oil on Abdominal Obesity

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women between 25 and 55 years Necessary cooperation in taking medicine Women suffering from abdominal obesity Waist circumference greater than 80 cm The possibility of following up patients Fill out a consent form by patients Not pregnant

Exclusion criteria:
Not using another topical drug that interferes with the effect of the studied drug Use other weight loss methods Medical condition that prohibits aerobic exercise Patients who do professional sports activities Patients on a weight loss diet History of allergic reaction to topical use of Chamomile oil and Dill oil The presence of an active skin lesion in the study area Women who intend to become pregnant during the treatment period Pregnant women Patient dissatisfaction Hypothyroidism and uncontrolled diabetes mellitus History of using steroid drugs in the last three months

Age
From **25 years** old to **55 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into case and control groups by random allocation method. block randomization method and table of random numbers are used to prepare the random list. It is taken in the way that we design a random block with 6 rows and 10 columns and write down the number of 30 letters A and 30 letters B randomly in its houses. With the first patient's visit, the first cell from row 1 of column 1 is selected and assigned to the intervention or control group based on the letter in the patient's cell, and then we draw a line on the corresponding letter with the selected meaning. We do the same for the rest of the patients to finally reach the determined sample size. We made 60 cards and write letter A on 30 for intervention and on the other 30 letter B for the control group. Then put them inside the envelope with aluminum wrap and put in a box. At the time of patient arrival, one of the envelopes randomly will be selected and open it, based on selected letter (A or B) patients will be assigned to intervention or control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The intervention group will receive a can of chamomile and dill oil, and the placebo group will receive a can of sesame oil. The medicine of both groups is ready to be delivered in similar packaging and in a can with dull color. The lid of the placebo oil can is smeared with chamomile and dill essential oil.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Iran University of Medical Sciences

Street address
Iran University of Medical Sciences., Hemmat Highway

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Tehran

Province
Tehran

Postal code
1449614535

Approval date
2022-05-10, 1401/02/20

Ethics committee reference number
IR.IUMS.REC.1401.133

Health conditions studied

1

Description of health condition studied
Obesity

ICD-10 code
E65-E68

ICD-10 code description
Obesity and other hyperalimentation

Primary outcomes

1

Description
Abdominal circumference size

Timepoint

At the beginning of the intervention, then every three weeks until the end of the intervention

Method of measurement

Tape measure

2

Description

Abdominal subcutaneous fat thickness in three areas: the thickness of the horizontal skin fold at 3 cm from the navel and 1 cm below it on the right side, the thickness of the skin fold above the navel at the midpoint of the line between the breast and navel junction, the thickness of the left supra iliac skin fold above the iliac crest. In the left midaxillary line

Timepoint

At the beginning of the intervention, then every three weeks until the end of the intervention

Method of measurement

Skinfold Caliper

Secondary outcomes

1

Description

Body weight

Timepoint

At the beginning of the study and then every three weeks until the end of the study

Method of measurement

Digital weight scale

2

Description

Body Mass Index

Timepoint

At the beginning of the study and then every three weeks until the end of the study

Method of measurement

Dividing people's weight (in kilograms) by the square of height (height times height in meters)

Intervention groups

1

Description

Intervention group: In the intervention group for 6 weeks, a combination of chamomile oil and dill oil once a day in the amount of 2 cc per square meter (in such a way that the entire abdominal area except for the radius of 2 centimeters around the navel (10 square centimeters) is completely lubricated and covered with a thin layer of oil) without massaging the area. After using the oil, cover the area with a plastic cover and have 30 minutes of aerobic activity (fast walking in such a way that the heart rate and breathing rate increase and sweating occurs) and the plastic cover is removed from the abdomen after the aerobic activity.

Category

Treatment - Drugs

2

Description

Control group: The control group received placebo oil for 6 weeks once a day in the amount of 2 cc per square meter (in such a way that the entire abdominal area except for the radius of 2 centimeters around the navel (10 square centimeters) was completely greased and covered with a thin layer of oil. be) used without massaging the area. After using the oil, cover the area with a plastic cover and have 30 minutes of aerobic activity (fast walking in such a way that the heart rate and breathing rate increase and sweating occurs) and the plastic cover is removed from the abdomen after the aerobic activity.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Behesht Iranian traditional medicine healthcare centre

Full name of responsible person

Maryam Bashiri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Institute for Islamic and Complementary Medicine (RICM)

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
Research Institute for Islamic and Complementary Medicine (RICM)

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

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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