Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Cryolipolysis and Diet on Metabolic Factors and Fat Layer Thickness

Protocol summary

Study aim
Effect of Cryolipolysis and Diet on Metabolic Factors and Fat Layer Thickness

Design
Randomized controlled phase 3 clinical trial, with parallel groups, with blinded data analyzer, on 50 participants. For randomization, random number table will be used.

Settings and conduct
،his study will be performed in the nutrition clinic of Ghaem Hospital in Mashhad. The subjects included overweight women with a body mass index between 25 and 29.9 and no underlying disease and cellulitis. After obtaining informed consent, 4 cc of fasting blood is taken from the brachial vein (10-12 hours of fasting). Individuals will then be visited by a nutritionist and given nutritional advice. In the cryolipolysis intervention group, it is performed in 2 sessions, the first week and the fourth week. Each session will include 60 minutes in each position. Diet and visit to a nutritionist and anthropometric indices will be done 3 times, beginning of the study, week 4 and end of the study (week 8) (intervention and control group). Ultrasound and examination of the thickness of the fat layer are performed twice, at the beginning and end of the study. Blood samples are taken before the start of the study and at week 8. The physical satisfaction questionnaire will be taken at the beginning and end of the study.

Participants/Inclusion and exclusion criteria
Female aged 18-65 with BMI 25-29.9 without cellulitis and underlying disease whom complete informed consent.

Intervention groups
The intervention group is participants whom undergoing cryolipolysis and diet and the control group is participants whom under diet.

Main outcome variables
anthropometric measurements; serum lipid profile; blood glucose; serum hs-CRP; fat layer thickness according to ultrasound; physical satisfaction questionnaire.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200927048848N1**
Registration date: **2020-09-30, 1399/07/09**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-30, 1399/07/09**
Update count: **0**

Registration date
2020-09-30, 1399/07/09

Registrant information

Name
Mahmoud Ebrahimi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3854 5985

Email address
ebrahimimh@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-22, 1399/07/01

Expected recruitment end date
2021-01-20, 1399/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effect of Cryolipolysis and Diet on Metabolic Factors and Fat Layer Thickness

Public title
Effect of Cryolipolysis and Diet on Metabolic Factors and Fat Layer Thickness
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18-25 Informed consent Body mass index (BMI) between 25-29.9
Exclusion criteria:
underlying disease
Age
From **18 years** old to **65 years** old
Gender
Female

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done in a simple way. Random numbers will be obtained individually using the Randomaization.com random number table. A sealed envelope will be used to conceal the allocation of participants. For this purpose, one of the members of the research team prepares and prints the obtained random numbers and puts them in the envelope. The lids of the envelopes will be sealed and its contents will not be visible from the outside. First, the purpose of the study is explained to the person who meets the conditions, and the person, if desired, signs the informed consent form and takes an envelope, and then opens it and enters the intervention or control group based on the contents of the envelope. .
Blinding (investigator's opinion)
Single blinded
Blinding description
Findings obtained from the study will be entered and coded in SPSS software. In the file that will be provided to the analyst for statistical analysis, the different modes of all qualitative variables, including the type of group (control intervention) will be coded with numbers, so the type of group studied will be unknown to the analyst.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of Mashhad University of Medical Sciences
Street address
Gharshi building, Daneshgah street
City
Mashhad
Province
Razavi Khorasan
Postal code
1394491388
Approval date
2020-07-18, 1399/04/28
Ethics committee reference number
IR.MUMS.REC.1399.372

Health conditions studied

1

Description of health condition studied
overweight (BMI between 25 and 29.9)
ICD-10 code
E66.3
ICD-10 code description
Overweight

Primary outcomes

1

Description
anthropometric measurements
Timepoint
At the beginning of the study, week 4, at the end of the study (week 8)
Method of measurement
Body composition analyzer of BIA770 made in South Korea

2

Description
serum lipid profile including TG, HDL-C, LDL-C, total cholesterol, bloods glucose and hs-CRP
Timepoint
At the beginning of the study and at the end of the study (week 8)
Method of measurement
BT-3000 auto analyzer

3

Description
fat layer thickness
Timepoint
At the beginning of the study and at the end of the study

(week 8)
Method of measurement
ultrasound

4

Description
body satisfaction
Timepoint
At the beginning of the study and at the end of the study (week 8)
Method of measurement
body satisfaction questionnaire (Kessler)

Secondary outcomes

empty

Intervention groups

1

Description
In the cryolipolysis intervention group, the first week and the fourth week are performed in 2 sessions, each session will include 60 minutes in each position. In this study, Fusiomed model cryolipolysis machine with BIO TEC brand made in Italy is used. After cryolipolysis, massage will be performed on the cryo site for two minutes. Diet assessment and visit to a nutritionist will be done 3 times, at the beginning of the study, week 4 and the end of the study (week 8).
Category
Treatment - Devices

2

Description
In the control group, diet assessment and visit to a nutritionist will be done 3 times, at the beginning of the study, week 4 and at the end of the study (week 8).
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem hospital nutrition clinique
Full name of responsible person
Mahmood Ebrahimi
Street address
nutrition clinique, Ghaem hospital, Sariati square
City
Mashhad
Province
Razavi Khorasan
Postal code
9176699565
Phone
+98 51 3840 0000
Email
EbrahimiMH@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Garshi building-Daneshgah street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Email
tafaghodim@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Mahmood Ebrahimi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
Street address
cardiovascular departement, Imam Reza hospital
City
Mashhad
Province

Razavi Khorasan
Postal code
913791331
Phone
0098 51 3854450
Email
EbrahimiMH@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mahmood Ebrahimi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
Street address
Cardiovascular departement, Imam Reza hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
913791331
Phone
0098 51 3854450
Email
EbrahimiMH@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mahmood Ebrahimi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
Street address
Cardiovascular departement, Imam Reza hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
913791331
Phone
0098 51 3854450
Email
EbrahimiMH@mums.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
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
Not applicable