

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 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

This 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 Randomization.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 committee 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

+98 51 3840 0000

**Email**

EbrahimiMH@mums.ac.ir

**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**

**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

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913791331  
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0098 51 3854450  
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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  
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Subspecialist  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**

Mahmood Ebrahimi  
**Position**  
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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

Not applicable