

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Effect of Cryolipolysis, Ultrasound Cavitation and Radio Frequency on fat thickness as adiposity-Selective non\_invasive fat reduction

#### Protocol summary

##### Study aim

Evaluation of combined effect of Cryolipolysis with Ultrasound Cavitation and RF on body composition To evaluate the efficacy and safety of Cryolipolysis, UC and RF for subcutaneous fat reduction To determine whether multiple same treatments (Cryolipolysis plus both Cryo and UC and RF) result in changes in body composition

##### Design

Clinical trials. parallel groups.Randomized

##### Settings and conduct

Participants are selected from 18-65 years' women who are referred to the center based for evaluation of Inclusion and Exclusion criterias, The services will be completely free of charge. Patients' information such as age, weight, BMI, medical history is measured by a trained technician before the start of treatment, and the body scan is used to evaluate anthropometric and body composition indicators.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria:body mass index (BMI) greater than 27 kg/m2.age between 18 and 65-years old.Weight change less than 5% during the last month.Sign a Consent Form. non inclusion critria :Pregnancy.lactating in the first 6 months.Any skin disease.Taking medications or weight control supplements now or last month

##### Intervention groups

Participants will randomly assigned to 2 groups of 26 participants. Group one cryolipolysis and group two combination of cryolipolysis and ultrasound cavitation. Group 1 will be referred to 8 sessions with a week's interval to perform cryolipolysis. Group 2 will receive 8 steps with a distance of one second under the cryolipolysis and for stage with a two week interval for ultrasound cavitation.

##### Main outcome variables

waist circumference Fat mass of trunk BMI Weight

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110726007117N8**

Registration date: **2019-09-17, 1398/06/26**

Registration timing: **retrospective**

Last update: **2019-09-17, 1398/06/26**

Update count: **0**

##### Registration date

2019-09-17, 1398/06/26

##### Registrant information

##### Name

Majid Ghayour Mobarhan

##### Name of organization / entity

Mashhad University of Medical Sciences,

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1822 8573

##### Email address

ghayourm@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-11-02, 1397/08/11

##### Expected recruitment end date

2019-05-20, 1398/02/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Effect of Cryolipolysis, Ultrasound Cavitation and Radio Frequency on fat thickness as adipocyt-Selective non\_invasive fat reduction

## Public title

Effect of non-invasive devices on fat reduction

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

BMI more than 25 Age between 18 and 65 years

### Exclusion criteria:

Pregnancy Lactation Active implant device such as pacemaker, defibrillator or drug delivery Tooth infection History of previous surgery in the desired area History of stroke or facial paralysis (Bell's palsy) Botulinum toxin or injection of aesthetic drugs in the area (abdomen) during the last 6 months. Treatment with dermal fillers, radioactive methods or laser

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

4

## Groups that have been masked

- Data analyser

## Sample size

Target sample size: **52**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization type: permuted block randomization  
Blocking is generally done in two ways that either the size of the groups is equal or the size of the groups is different and in this study the groups are equal. Random allocation software is used for randomization. Sealed envelopes with a random sequence are used to hide the random allocation. Based on the sample size of the study, some non-transparent envelopes were prepared (in order to avoid envelope content), and each of the random sequences was generated on a fixed-name card and a more transparent envelope card. For the purpose of random order retrieval, the outermost layer of the numbered packets is assigned the same order. Finally the lid envelope lid is placed in boxes, respectively. At the beginning of registration, Based on the order of entry of the eligible participants into the study, one of the packages named in the open order and its assigned group of participants is revealed. A person who do a randomization is different with the person who studying the participants in terms of entry and exit criteria and registered them to study.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

in this study data analyzer will be blind

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

"Ethics committee of National Institute of Medical Research Development" (NIMAD)

##### Street address

No 21, Besat Alley, West Fatemi ST, Tehran Town

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۱۹۶۹۳۱۱۱

#### Approval date

2018-06-16, 1397/03/26

#### Ethics committee reference number

IR.NIMAD.REC.1397.224

## Health conditions studied

### 1

#### Description of health condition studied

Overweight and obesity

#### ICD-10 code

E66

#### ICD-10 code description

Overweight and obesity

## Primary outcomes

### 1

#### Description

"Anthropometric indices"

#### Timepoint

"before and after of the intervention"

#### Method of measurement

"bio impedance analyser(BIA)"

## Secondary outcomes

### 1

#### Description

"Examine the satisfaction of the body composition"

#### Timepoint

before and after of the intervention

#### Method of measurement

"body satisfaction questionnaire(BSQ)"

## 2

### **Description**

"psychological distress scale evaluation"

### **Timepoint**

"before and after of the intervention"

### **Method of measurement**

kessler psychological distress scale k10 score interpretation

## 3

### **Description**

"Lipid profile measurement"

### **Timepoint**

"before and after of the intervention"

### **Method of measurement**

"blood sampling"

## 4

### **Description**

"Liver enzyme measurement"

### **Timepoint**

"before and after of the intervention"

### **Method of measurement**

"blood sampling"

## **Intervention groups**

### 1

#### **Description**

Intervention Group will receive combined cryolipolysis and ultrasound cavitation. People who entered to the this group will go to 8 times under cryolipolysis and 4 times with a 2-week interval for Ultrasound cavitation. To evaluate the body composition, BIA model 770 machine The construction of South Korea will be used. The Fusiomed Cryolipolysis device will be used with the BIO TEC brand in Italy, and will be used ultrasound cavitation ESM-4500ME model craft maker Mega Son, a South Korean brand.

#### **Category**

Treatment - Devices

### 2

#### **Description**

Control group: Cryolipolysis group. Entrants to this group will be have eight times a week for cryolipolysis.

#### **Category**

Treatment - Devices

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Ghaem Hospital

##### **Full name of responsible person**

Majid Ghayour-Mobarhan

#### **Street address**

No.1, Parastar Ave., Ahmad abad Blvd. Nutrition Clinic of Ghaem Hospital in Mashhad, Iran

#### **City**

Mashhad

#### **Province**

Razavi Khorasan

#### **Postal code**

91766-99199

#### **Phone**

+98 51 3840 0000

#### **Email**

Qaem.Medical.Center@mums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

National Institute for Medical Research Development (NIMAD)

##### **Full name of responsible person**

Mohadeseh Eskandari

##### **Street address**

No.21, Besat alley, west Fatemi st, Tehran

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

۱۴۱۹۶۹۳۱۱۱

##### **Phone**

+98 21 6693 8037

##### **Email**

nimad@research.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

National Institute for Medical Research Development (NIMAD)

#### **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**

Majid Ghayour Mobarhan

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Biochemistry & Nutrition Research Center,  
Cardiovascular Research Centre, Avicenna (Bu-Ali)  
Research Institute, Mashhad University of Medical  
Sciences (MUMS), Mashhad, Iran.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**Phone**

+98 51 3882 8888

**Email**

ghayourm@mums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Majid Ghayour Mobarhan

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

No. 2, Nutrition Department, school of Medicine,  
Mashhad University of Medical Science campus, Azady  
square, Mashhad, Khorasan Razavi, Iran

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

1394491388

**Phone**

+98 51 3841 2081

**Email**

ghayourm@mums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hamed Khedmatgozar

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

**Street address**

No. 2, Vakil Abad Ave., Azadi square., Ferdowsi  
University of Mashhad., School of Medicine., Nutrition  
Department

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**Phone**

+98 51 3882 8888

**Email**

khedmatgozarh961@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**

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