

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)

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+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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Institute for Medical Research Development (NIMAD)

Full name of responsible person

Mohadeseh Eskandari

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

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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

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,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Professor

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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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

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