Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Cryolipolysis, Ultrasound Cavitation and Radio Frequency on fat thickness as adipocity-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
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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 adipocity-Selective non_invasive fat reduction

Public title
Effect of non-invasive devises 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 model770 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 usedultrasound 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
Street address
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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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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