Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of Acoustic Wave Therapy added to nutritional diet and nutritional diet alone on weight and abdominal fat among women with Body Mass Index (BMI) greater than 30 Kilogram per square meter squared: a clinical trial.

Protocol summary

Summary

Objectives: In this single-blind, clinical trial, we try to determine the effects of “Acoustic Wave Therapy” on abdominal fat and weight of people with obesity in comparison to the control group. Design: The sample size would be 100 women in the age range of 35-45 years with a BMI of >30 kilogram per square meter. We will allocate the participants to two groups of cases and controls by convenient sampling from the population of people who have been referred to the clinic. The participants need to satisfy the two above-said criteria and have cellulite type II in the abdominal skin. Methods: The duration of the study will be 1.5 months. We will measure or calculate the body composition of the participants include whole body fat and also the fat mass in the abdominal region, weight, waist circumference and Body Mass Index before and after the study period. Fifty person in the case group will take diet plus aerobic exercise and acoustic wave therapy on abdomen region and fifty person in control group will take diet plus aerobic exercise without acoustic wave therapy. At the beginning and after 1.5 months of treatment we will measure changes of weight, whole body fat, abdominal fat and wrist circumference. Intervention: Case group Will have weight loss diet (1200-1500 Kcal with 55% carbohydrate, 20% protein and 20% fat)+one hour aerobics exercise+"Acoustic Wave Therapy" on abdominal site for 10 sessions, twice a week, 4000 pulses, frequency of 16 Hz, energy of 1.4 to 2.6 bar by D-ACTOR 200(STORZ MEDICAL AG, Switzerland). Case group: Will have weight loss diet (1200-1500 Kcal with 55% carbohydrate, 20% protein and 20% fat)+one hour aerobics exercise, without using "Acoustic Wave Therapy". Main outcome measures: The body composition analyzer measures the whole fat mass and abdominal fat mass through measuring and comparing the bio-impedance among different tissues. Weight will be measured using a scale and waist circumference will be measured by a meter strip. BMI will be calculated through weight divided by height squared (Kg/m2) before and after treatment. Inclusion criteria: Female; age range 35-45 years; Body Mass Index>30 kilogram/m2; diagnosed with the cellulite grade II in the skin of abdomen. Exclusion criteria: Diabetes; hypertension; cardiovascular disease; liver disease; blood clotting disorders; hypothyroidism; varicose vein;, skin disease; cancer; favism; asthma; using some blood- thinning medications.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081629398N1**
Registration date: **2016-09-18, 1395/06/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-09-18, 1395/06/28

Registrant information

Name

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Name of organization / entity

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Recruitment status
Recruitment complete
Funding source
Vice Chancellor of Research, Kashan University Medical of Sciences

Expected recruitment start date
2016-07-22, 1395/05/01
Expected recruitment end date
2017-03-19, 1395/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of Acoustic Wave Therapy added to nutritional diet and nutritional diet alone on weight and abdominal fat among women with Body Mass Index (BMI) greater than 30 Kilogram per square meter squared: a clinical trial.

Public title
The effect of Acoustic Wave Therapy on weight and abdominal fat in obese people
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Female; age range 35-45 years; Body Mass Index (BMI)>30 kilogram per square meter; diagnosed with the cellulite grade II is skin criteria of abdomen region. Exclusion criteria: Diabetes; hypertension; cardiovascular disease; liver disease; blood clotting disorders; hypothyroidism; varicose veins; skin disease; cancer; favism; asthma; using some blood-thinning medications like: warfarin; heparin; aspirin; omega-3 fatty acids.
Age
From **35 years** old to **45 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Non-probability sampling; Accidental or Convenience sampling. We will accept the participants by convenient sampling from the population of people who have been referred to the clinic. The participants need to satisfy the including criteria.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kashan University of Medical Sciences
Street address
Vice Chancellor for Research, Kashan University Medical of Sciences, 5th kilometer of Qotb –e Ravandi Blvd.
City
Kashan
Postal code
87159-88141
Approval date
2016-07-05, 1395/04/15
Ethics committee reference number
IR.KAUMS.REC.1395.34

Health conditions studied

1

Description of health condition studied
Obesity
ICD-10 code
E66.0
ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
Weight
Timepoint
Before and 1.5 months after intervention
Method of measurement
kilogram, with scale

2

Description
Body Mass Index (BMI)
Timepoint
Before and 1.5 months after intervention
Method of measurement
kilogram/square meter(Kg/m2), calculated by using weight/hight2 formula

3

Description
whole body fat
Timepoint
Before and 1.5 months after intervention
Method of measurement
kilogram, with body composition analyzer

4

Description
abdominal fat
Timepoint
Before and 1.5 months after intervention
Method of measurement
kilogram, with body composition analyzer

5

Description
waist circumference
Timepoint
Before and 1.5 months after intervention
Method of measurement
centimeter, by strip meter

Secondary outcomes

empty

Intervention groups

1

Description
Will take weight loss diet (1200-1500 Kcal with 55% carbohydrate, 20% protein and 20% fat)+one hour aerobics exercise+"Acoustic Wave Therapy" for abdominal site, 4000 pulses, frequency of 16 Hz, energy of 1.4 to 2.6 bar by D-ACTOR 200(STORZ MEDICAL AG, Switzerland) for 10 sessions, twice a week
Category
Treatment - Other

2

Description
Case group: Will take weight loss diet (1200-1500 Kcal with 55% carbohydrate, 20% protein and 20% fat)+one hour aerobic exercise, without using "Acoustic Wave Therapy".
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Naghavi Hospital-Kashan University of Medical Sciences
Full name of responsible person
Shokouh Sarbolouki
Street address
Shahid Rajaei Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor of Research, Kashan University Medical of Sciences
Full name of responsible person
Gholam Ali Hamidi (Ph.D)
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5th kilometer of Qotb –e Ravandi Blvd
City
Kashan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor of Research, Kashan University Medical of Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty