

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 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

Shokouh Sarbolouki

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 913 361 0275

Email address

sarbolouki@kamus.ac.ir

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.

AgeFrom **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

City

Kashan

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)

Street address

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**Name of organization / entity**

Kashan University Medical of Sciences

Full name of responsible person

Shokouh Sarbolouki

Position

Dietitian and nutritionist

Other areas of specialty/work**Street address**

No. 53, Amirkabir Street

City

Kashan

Postal code

8719695866

Phone

+98 31 5531 1099

Fax**Email**

sarbolouki@kaums.ac.ir; shokoohs@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Shokouh Sarbolouki

Position

diet and nutrition Ph.D.

Other areas of specialty/work

Street address

No. 53, Amirkabir Street

City

Kashan

Postal code

8719695866

Phone

+98 31 5531 1099

Fax

Email

sarbolouki@kaums.ac.ir; shokoohs@yahoo.com

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Postal code

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+98 31 5531 1099

Fax

Email

sarbolouki@kaums.ac.ir; shokoohs@yahoo.com

Web page address

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

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person