Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of microwaves platform on reduction of abdominal subcutaneous fat and plasma leptin and adiponectin level.

Protocol summary

Study aim
Evaluation of the effectiveness of microwave technology on reducing abdominal fat and plasma levels of Leptin and Adiponectin

Design
This is an interventional study. After obtaining informed consent from participants and determining the indications of the appropriateness of microwave, 30 healthy people aged 18 to 65 years with overweight and body mass index (BMI) of less than 30 kg/m2 are included in the study.

Settings and conduct
This study will be performed in an obesity treatment clinic. In the first session, demographic information and anthropometric parameters are measured. 5 cc of non-fasting venous blood sample is taken. Participants are given an isocaloric diet. Then treated with microwaves. This process is repeated in the second session of the intervention (20 days after the first session) and also 20 days after the second and third intervention. In order to control dietary intakes, food frequency questionnaire is completed. In order to control the energy consumption of individuals, the IPAQ body activity questionnaire verified for the Iranian population will be completed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Filling in the moral consent or the absence of a legal prohibition to intervene, Age 65-18 years, Body mass index less than 30 kg/m2

Intervention groups
According to the standard treatment protocol, patients are treated with microwave technology (2.5 GHz radiofrequency) using Onda device (Onda, DEKA technology, Florence, Italy) for 3 sessions with an interval of 20 days.

Main outcome variables
Body mass index; Percentage of body fat; waist circumference: Subcutaneous adipose tissue thickness; Intra-abdominal adipose tissue volume; Blood levels of adiponectin, leptin and lipoprotein lipase; Prooxidane-Antioxidant Balance (PAB); Daily calorie intake; Daily physical activity

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20181010041303N1**
Registration date: **2020-11-15, 1399/08/25**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-15, 1399/08/25**
Update count: **0**

Registration date
2020-11-15, 1399/08/25

Registrant information
Name
mahsa malekahmadi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 8823 1578
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malekahmadim951@mums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-10-27, 1399/08/06
Expected recruitment end date
2020-11-26, 1399/09/06
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of microwaves platform on reduction of abdominal subcutaneous fat and plasma leptin and adiponectin level.

Public title
Effect of microwaves platform on reduction of abdominal subcutaneous fat

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy people aged 18 to 65 years overweight with a body mass index (BMI) of less than 30 kg / m2 Intra-abdominal fat volume less than 12 kg Absence of active cancer (chemotherapy / radiotherapy) in the last 6 months No non-invasive lipolysis in the abdomen or other parts of the body in the last 3 months completing a moral consent or no legal prohibition on intervention Absence of abdominal surgery in the last 6 months Absence of acute heart disease in the last 6 months Absence of liver cirrhosis in the last 6 months

Exclusion criteria:
Pregnancy and lactation Use of anticoagulants (other than aspirin) Use of isotretinoin drugs Secretion skin lesions and active eczema on the surface of the abdominal skin

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
School of Medicine, east door of the university campus, Azadi Square, Mashhad, Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
0071151303

Approval date
2020-10-26, 1399/08/05

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.444

Health conditions studied

1

Description of health condition studied
overweight

ICD-10 code
E66.3

ICD-10 code description
Overweight

Primary outcomes

1

Description
Body mass index: ratio of weight (kg) to height2 (m2)

Timepoint
At the beginning of the study (before the intervention) and 20, 40 and 60 days after the start

Method of measurement
Using the formula weight (kg)/ height 2 (m2)

2

Description
Percentage of body fat

Timepoint
At the beginning of the study (before the intervention) and 20, 40 and 60 days after the start

Method of measurement
with body analyzer

3

Description
waist circumference

Timepoint
At the beginning of the study (before the intervention) and 20, 40 and 60 days after the start

Method of measurement
Using a tape measure

4

Description

The thickness of the subcutaneous fat tissue of the abdomen

Timepoint

At the beginning of the study (before the intervention) and 20, 40 and 60 days after the start

Method of measurement

By ultrasound device

5

Description

Intra-abdominal adipose tissue volume

Timepoint

At the beginning of the study (before the intervention) and 20, 40 and 60 days after the start

Method of measurement

By ultrasound device

6

Description

serum levels of adiponectin

Timepoint

At the beginning of the study (before the intervention) and 20, 40 and 60 days after the start

Method of measurement

ELISA kit

7

Description

Serum levels of lipoprotein lipase

Timepoint

At the beginning of the study (before the intervention) and 20, 40 and 60 days after the start

Method of measurement

ELISA kit

8

Description

Prooxidane-Antioxidant Balance (PAB)

Timepoint

At the beginning of the study (before the intervention) and 20, 40 and 60 days after the start

Method of measurement

By calorimetric method

9

Description

Serum levels of leptin

Timepoint

At the beginning of the study (before the intervention) and 20, 40 and 60 days after the start

Method of measurement

ELISA kit

Secondary outcomes

1

Description

daily calorie intake

Timepoint

baseline

Method of measurement

food frequency questionnaire

2

Description

daily physical activity

Timepoint

baseline

Method of measurement

IPAQ questionnaire

Intervention groups

1

Description

Intervention group:According to the standard treatment protocol, patients are treated with microwave technology (2.5 GHz radiofrequency) using Onda device (Onda, DEKA technology, Florence, Italy) for 3 sessions with an interval of 20 days. Participants are also given an isocaloric diet. This process is repeated in the second session of the treatment intervention (20 days after the first session) and also 20 days after the second and third intervention.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Behbood clinic

Full name of responsible person

Abdolreza Norouzy

Street address

Behbood Clinic, corner of 14th Alley, the beginning of North Mofteh, Shahid Beheshti Ave, Tehran, Iran

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Tehran

Province

Tehran

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15877844611

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person
Abdolreza Norouzy
Street address
School of Medicine, east door of the university campus, Azadi Square, Mashhad, Iran
City
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Phone
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norouzya@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Artiman

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Abdolreza Norouzy
Position
Associated professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
School of Medicine, east door of the university campus, Azadi Square, Mashhad, Iran
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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