Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation the effect of high-power laser with two simultaneous wavelengths on weight and waist circumference in women with abdominal obesity (Pilot Study)

Protocol summary

Study aim

Determining the effect of high power laser with two simultaneous wavelengths on weight and abdominal circumference in woman with abdominal obesity

Design

Clinical trial with a control group with parallel groups, double blinded, phase 2, randomized on 40 participants will be conducted. randomized block method will be used for randomizing.

Settings and conduct

Intervention will be carried out with student at Dr Tahery`s Physiotherapy clinic in the form of 2 sessions per week up to 10 times. and study is double blinded.

Participants/Inclusion and exclusion criteria

The target population in this study is women between 25 and 50 years old who have abdominal obesity. The body mass index should be between 25 and 35, and they shouldn't be breastfeeding or menopausal. It is obvious that any of contraindications of high power laser such as malignancy, radiotherapy, having a pacemaker, ect ,will cause people to leave study. Also if the persona has a life- threatening disease in away that affects the results of study ; in consultation with a specialist doctor(project partner), she will be excluded from the study.

Intervention groups

The laser will be performed by a Novin high power laser device with a combined wavelength of 810 and 980 nm with at least 15 joules of energy per unit square area of the abdomen.the laser will be applied by holding a manual piece perpendicular to the abdomen and moving it from the top and left to the right and vice versa. The intervention will be conducted two days a week and up to 10 sessions in both groups. The control group will receive the laser on the abdomen in the same and similar conditions but with the laser off.

Main outcome variables

Weight- Abdominal circumference

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250318065125N1**
Registration date: **2025-07-25, 1404/05/03**
Registration timing: **prospective**

Last update: **2025-07-25, 1404/05/03**
Update count: **0**

Registration date

2025-07-25, 1404/05/03

Registrant information

Name

Neda Ghderi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

nedaghpt@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-23, 1404/06/01

Expected recruitment end date

2025-12-22, 1404/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation the effect of high-power laser with two simultaneous wavelengths on weight and waist circumference in women with abdominal obesity (Pilot Study)

Public title
Evaluating the effect of high power laser on weight and abdominal circumference

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women aged between 25 and 50 years old The circumference of the abdomen should be greater than and equal to 80 cm In the last three months, they have not used any other method, be in diet or physical activity, or any other method to lose weight or reduce abdominal fat. Home pregnancy test should be negative. Having a body mass index between 25 to 35

Exclusion criteria:
Having any of the high power laser contra-indications including: pregnancy, malignancy, radiotherapy in the last 4 to 6 months, pacemaker, abdominal skin sensation disorders and abnormal sensitivity to light. Having a history of abdominal surgery or liposuction Breastfeeding Menopause Having tattoo, trauma or any damage of abdominal skin. Suffering from any serious diseases in the body systems that endangers the person`s health and has the possibility of interfering with the results of the current research

Age
From **25 years** old to **50 years** old

Gender
Female

Phase
2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done by a random block method and by a person rather than the researcher and the evaluator in 2 groups of 20 people. in this study, we will have 10 blocks of four, in such a way that 2 people from the intervention group and 2 people from the control group will be randomly placed in each block of 4.

Blinding (investigator's opinion)
Double blinded

Blinding description
Planning for double- blinding will be such that the participants, the evaluator ,the person who performs the intervention (researcher) and the Data analyser will not be aware of the grouping method. participants know that they will be in 2 different groups but they will be completely unaware of the grouping and which group they are in. the researcher (student) is not aware of the process of evaluating the people of both groups and finally the evaluator will be unware of intervention and grouping process .

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Hezar Jerib street, Isfahan University of Medical Sciences, ethic committee of university

City
Isfehan

Province
Isfehan

Postal code
81746-73461

Approval date
2025-07-16, 1404/04/25

Ethics committee reference number
IR.MUI.REC.1404.023

Health conditions studied

1

Description of health condition studied
Abdominal obesity

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Abdominal circumference

Timepoint
Before the treatment , at the end of the fifth session, at the end of the tenth session and the end of one month follow up period

Method of measurement
Special Tape measure for measuring abdominal circumference

2

Description
Weight
Timepoint
Before the treatment , at the end of the fifth session, at the end of the tenth session and the end of one month follow up period.
Method of measurement
Digital Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: High power laser- the high power laser device is from Novin Engineering -Medical Company and model 885G, its maximum output power is 15 watts and it emits 2 wavelengths of 810 & 980 nm simultaneously. the radiation time will be calculated based on the area of the abdominal area measured with a tape and according to the relevant formula.
Category
Treatment - Devices

2

Description
Control group:
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Navid Taheri's physiotherapy clinic
Full name of responsible person
Dr.Navid Taheri
Street address
1st floor, Jahan Soltan building,Mohtasham Kashani Ave, Hakim nezami street, Isfahan.
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Sponsors / Funding sources

1

Sponsor
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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
Esfahan University of Medical Sciences
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
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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