Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluating the effectiveness of carboxytherapy in decreasing the thickness of abdominal subcutaneous fat through clinical and ultrasonographical studies

Protocol summary

Study aim
Assessment of efficacy of carboxytherapy in decreasing thickness of abdominal subcutaneous fat in ultrasonographic view, Assessment of efficacy of carboxytherapy in decreasing density of abdominal subcutaneous fat in ultrasonographic view, Assessment of efficacy of carboxytherapy in reduction of BMI, Assessment of efficacy of carboxytherapy in reduction of waist circumference, Assessment of efficacy of carboxytherapy in reduction of waist/hip ratio, Assessment of efficacy of carboxytherapy in reduction of abdominal sagging objectively and subjectively

Design
Clinical trial, 30 subjects, The body (left/right) will be randomly divided into two groups and carboxytherapy will be used for one side and the opposite side will be left untreated.

Settings and conduct
The abdominal wall is proportionally divided into two areas, right and left. Carboxytherapy will be done on one side (intervention group) and the other side (control group) will be left untreated. Valiasr Arak Hospital.

Participants/Inclusion and exclusion criteria
Ages > 18 years old, Both genders, BMI ≥ 25 kg/m2, waist circumference greater than 102 Cm in men and 88 Cm in women, waist/hip ratio greater than 0.9 in men and 0.85 in women, the presence of abdominal sagging, Pregnancy, Breast feeding, history of smoking and alcohol and drug abusing, Medication (also including supplimentary agents) whitin 6 weeks before the study initiation, Any lipolytic treatment or procedure at the site of study within one year before study initiation, Any systemic disorder such as diabetes mellitus, kidney diseases, cardiac diseases, respiratory diseases, liver diseases, severe anemia, etc. Any diluents and antyconvulsant drugs

Intervention groups
30 people with high levels of abdominal fat

Main outcome variables
Clinical assessment, BMI, waist circumference, waist/hip ratio, abdominal sagging objectively and subjectively, Ultrasonographic assessment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220517054900N1**
Registration date: **2022-07-10, 1401/04/19**
Registration timing: **retrospective**

Last update: **2022-07-10, 1401/04/19**
Update count: **0**

Registration date
2022-07-10, 1401/04/19

Registrant information

Name
mahsa rafiee

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3366 4652

Email address
mahsarafiee76@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-28, 1401/03/07

Expected recruitment end date
2022-05-28, 1401/03/07

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effectiveness of carboxytherapy in decreasing the thickness of abdominal subcutaneous fat through clinical and ultrasonographical studies

Public title
Evaluating the effectiveness of carboxytherapy in decreasing the thickness of abdominal subcutaneous fat through clinical and ultrasonographical studies
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
BMI ≥ 25 kg/m2 Waist circumference greater than 102 Cm in men and 88 Cm in women Waist/Hip ratio greater than 0.9 in men and 0.85 in women Abdominal sagging
Exclusion criteria:
Pregnancy Breast feeding History of smoking, alcohol and drug abuse Medication (also including supplimentary agents) within 6 weeks before the study initiation Any lipolytic treatment or procedure at the site of study within one year before the study initiation Any systemic disorder such as diabetes mellitus, kidney diseases, cardiac diseases, respiratory diseases, liver diseases, severe anemia, etc. Using diluent and anticonvulsant drugs
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
In each case, the abdominal wall is proportionally divided into two areas, right and left. Carboxytherapy will be performed on one side (case group) and the other side (control group) will be left untreated. Case and control groups in each person are randomly selected by tossing a coin.
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 Arak University of Medical Sciences
Street address
Arak University of Medical Science
City
Arak
Province
Markazi
Postal code
3819693345
Approval date
2022-04-17, 1401/01/28
Ethics committee reference number
IR.ARAKMU.REC.1401.027

Health conditions studied

1

Description of health condition studied
The effectiveness of carboxytherapy in reducing the thickness of abdominal subcutaneous fat
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Clinical evaluation objectively and subjectively
Timepoint
Time 0, before each session and 2 weeks after the last session
Method of measurement
Visual and photographic findings

2

Description
BMI
Timepoint
Time 0, before each session and two weeks after the last session
Method of measurement
Meters and scales

3

Description
Waist circumference
Timepoint

Time 0, before each session and two weeks after the last session

Method of measurement

Meter

4

Description

Waist/hip ratio

Timepoint

Time 0, before each session and two weeks after the last session

Method of measurement

Meter

5

Description

Abdominal subcutaneous fat thickness and density

Timepoint

2 weeks after the last session

Method of measurement

Ultrasound machine

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the present study, carboxytherapy will be performed in 30 people with high abdominal fat by injecting CC 300 CO2 gas subcutaneously through a carboxytherapy device on one side of the abdomen. Based on the calibration pattern of Medione's carboxytherapy device, gas will be injected at a rate of 0.5 CC per shot and at a temperature of 40 degrees Celsius. In order to reduce the potential risk of CO2 penetration from the case side to the control side, we will start the treatment from the outermost part of the abdomen. This intervention is done in 5 sessions

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Mahsa Rafiee

Street address

Valiasr Hospital, Valiasr Square, Arak, Markazi Province, Iran

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3814957558

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pr_valiasr@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza kamali

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Mahsa Rafiee

Position

Medical intern

Latest degree

Medical doctor

Other areas of specialty/work

Medical student

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Mahsa Rafiee

Position
Medical intern

Latest degree
Medical doctor

Other areas of specialty/work
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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