

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of alpha-lipoic acid supplementation and Electrical isotonic contraction on Anthropometric parameters, body composition and Angiogenesis factor, sirtuin-1 and PGC1 α in obese people under weight loss regime

Protocol summary

Study aim

The effect of alpha-lipoic acid consumption and electrical isotonic contraction on anthropometric measures, body composition, serum levels of some angiogenesis, sirtuin and PGC1 α in obese subjects under weight loss regimen

Design

100 individuals will be randomly assigned to four groups (25 people).

Settings and conduct

Initially, information will be gathered from individuals using the information form, food intake information using the 24-hour feed recall, anthropometric measurements (weight, height, and waist circumference) and body composition (by BIA machine). At the beginning and the end of intervention, blood samples from each of the four groups will be taken at a rate of 10 cc. Serum levels of angiogenesis (VEGF, NO), serum serotonin, serum PGC1 α factor will be measured by ELISA method.

Participants/Inclusion and exclusion criteria

Criteria for entering the study: body mass index is between 30-40 kg / m²; age between 18-50. Exit criteria: changes in diet and physical activity; unwillingness to cooperate.

Intervention groups

Of a daily 2 capsule contains 600 mg of alpha-lipoic acid (an hour before lunch and dinner), along with a diet calculated to reduce weight, the second group in addition to weight loss diets, under the stimulation device Faradayk to three sessions of one hour per week, the third time in addition to weight loss diets daily, two capsules containing 600 mg of alpha-lipoic acid for 2 months and under stimulation device Faradayk and fourth twice daily placebo capsule containing 600 mg Warm wheat flour will be taken with a calorie-calorie diet for weight loss for 2 months.

Main outcome variables

Angiogenesis factors (VEGF, NO); serum serotonin factor; PGC1 α serum factor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131117015424N2**

Registration date: **2018-04-02, 1397/01/13**

Registration timing: **prospective**

Last update: **2018-04-02, 1397/01/13**

Update count: **0**

Registration date

2018-04-02, 1397/01/13

Registrant information

Name

MAjid Mohamadshahi

Name of organization / entity

Ahvaz Jundishapur University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 439 2836

Email address

mohamadshahi-m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-03, 1397/01/14

Expected recruitment end date

2018-06-19, 1397/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of alpha-lipoic acid supplementation and Electrical isotonic contraction on Anthropometric parameters, body composition and Angiogenesis factor, sirtunin-1 and PGC1 α in obese people under weight loss regime

Public title

The effect of alpha-lipoic acid supplementation and Electrical isotonic contraction on Anthropometric parameters, body composition and Angiogenesis factor, sirtunin-1 and PGC1 α in obese people under weight loss regime

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Body mass index is between 30-40 kg / m² Age between 18-50 Lack of systemic, inflammatory and chronic diseases (diabetes, hypertension, kidney) Lack of epilepsy Non-use of anti-inflammatory drugs, hormones, weight loss drugs and antioxidant and vitamin supplements Lack of Pregnancy and lactation Not having skin problems and allergies Not getting under a weight loss diet in the last 6 months Failure to follow a particular diet Lack of smoking and smoking

Exclusion criteria:

Systemic, inflammatory, liver, heart, kidney, and chronic diseases during the study Pregnancy Changes in diet and physical activity Unwillingness to cooperate

AgeFrom **18 years** old to **50 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant

Sample sizeTarget sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description

100 randomly selected individuals will be randomly assigned to four groups (25 people) by simple random digits.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants in the study

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz - Golestan - Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2018-01-13, 1396/10/23

Ethics committee reference number

IR.AJUMS.REC.1396.860

Health conditions studied**1****Description of health condition studied**

Obesity

ICD-10 code

E66.09

ICD-10 code description

Other obesity due to excess calories

Primary outcomes**1****Description**

VEGF Angiogenesis Factor

Timepoint

The beginning and the end of the study

Method of measurement

With ELISA method

2**Description**

NO Concentration

Timepoint

The beginning and the end of the study

Method of measurement

With ELISA method

3**Description**

Sirtuin Concentration

Timepoint

The beginning and the end of the study

Method of measurement

With ELISA method

4**Description**

PGC1 α Concentrations

Timepoint

The beginning and the end of the study

Method of measurement

With ELISA method

Secondary outcomes**1****Description**

Weight

Timepoint

The beginning and the end of the study

Method of measurement

Scales

2**Description**

Waist

Timepoint

The beginning and the end of the study

Method of measurement

Meter

3**Description**

Body Mass Index

Timepoint

The beginning and the end of the study

Method of measurement

Computing

4**Description**

Body Slim Percentage

Timepoint

The beginning and the end of the study

Method of measurement

BIA machine

5**Description**

Body Fat Percentage

Timepoint

The beginning and the end of the study

Method of measurement

BIA machine

Intervention groups**1****Description**

Intervention group: Individuals receive 2 capsules containing 600 mg of alpha-lipoic acid for 2 months (one hour before lunch and dinner), plus a diet with calories calculated to lose weight. The second group, in addition to having a weight loss diet, will be subjected to the induction of Faraday Machine for three sessions of an hour per week for 2 months. In addition to having a daily weight loss diet, people in the third group receive two capsules containing 600 mg of alpha-lipoic acid for 2 months and will be subjected to fadedic device stimulation.

Category

Treatment - Other

2**Description**

Control group: Each day, two capsules of the placebo will contain 600 milligrams of wheat flour and a diet with calories calculated to lose weight.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dr Majid Mohammadshahi's Clinic

Full name of responsible person

Majid Mohammadshahi

Street address

Ahvaz - Kianpars - West 15th Street - Phase 1 - IranPars Medical Complex - 3rd Floor - 9th and 10th Units

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mohmadshahi-m@ajums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Dr makhmalzadeh

Street address

Ahwaz - Golestan - Ahvaz Jundishapur University of Medical Sciences

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mohamadshahi-m@ajums.ac.ir

Web page address

<http://www.ajums.ac.ir>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Elahe zakizadeh

Position

Phd candidate of nutrition

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr majid mohamadshahi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Elahe zakizadeh

Position

PhD candidate of nutrition

Latest degree

Master

Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

All relevant data and tests will be published without mentioning the name.

When the data will become available and for how long

Data will be available after the publication of the articles.

To whom data/document is available

All researchers can access the data.

Under which criteria data/document could be used

The possibility of using this data to analyze and write an article will not be given to individuals.

From where data/document is obtainable

By emailing the accountability officer, they can access the documentation.

What processes are involved for a request to access data/document

After receiving the email, the file will be sent to the researchers.

Comments