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, sirtunin-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, sirtoin and PGC1α 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 PGC1α 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; PGC1α 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 andPGC1 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
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target 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
Ahwaz - 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
Sirtoin Concentration

Timepoint
The beginning and the end of the study
Method of measurement
With ELISA method

4

Description
PGC1α 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
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3338 9710
Email
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

City
Ahvaz

Province
Khouzestan

Postal code
61357-15794

Phone
+98 61 3338 9710

Email
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

Street address
Ahvaz.Gholestan highway.Ahvaz Jundishapur University of Medical Sciences

City
Ahwaz

Province
Khouzestan

Postal code
1579461357

Phone
+98 61 3333 9092

Email
e.zakizade.2010@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Dr majid mohamadshahi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Ahvaz.Gholestan highway.Ahvaz Jundishapur University of Medical Sciences

City
Ahwaz

Province
Khouzestan

Postal code
1579461357

Phone
+98 61 3333 9092

Email
mohamadshahi@ajums.ac.ir

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

Street address
Ahvaz,Gholestan highway,Ahvaz Jundishapur University of Medical Sciences

City
Ahwaz

Province
Khouzestan

Postal code
1579461357

Phone
+98 61 3333 9092

Email
e.zakizade.2010@gmail.com

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