Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Anti Inflammatory Properties of Combined Aquatic Extract of Ferulago Angulata Boiss with Aerobic Exercise on Pro Inflammatory Indices in Obese Males

Protocol summary

Study aim
The effects of aerobic exercise along with water extract of Ferulagoangulata consumption on serum levels of IL-6, IL-18, IL-1β and TNF-α in obese men

Design
Factorial group, Not blinded, randomised controlled trial, The study sample included 40 young obese men (30-40 years, Body Mass Index>30).

Settings and conduct
This research will be conducted at Abadan University of Medical Sciences. In this study, 40 young obese men (BMI > 30, 30-40 years old) will be selected randomly and randomly divided into four equal groups (n = 10), training, training-supplementation, supplementation and control. Participants in supplementary groups received 50 mg/ml Ferulago Angulata extracts daily for 12 weeks. Aerobic training program included 12 weeks of training, 3 sessions per week and each session was 20 minutes at 60-70% of Vo2max. Blood samples were taken from subjects 48 hours before and after the intervention in fasting state.

Participants/Inclusion and exclusion criteria
inclusion criteria: Male gender, BMI higher than 30, BMI higher than 30 Exclusion criteria: Having a history of a specific illness,Taking cigarettes and drugs, Taking medicine and supplement

Intervention groups
Training group:The aerobic training consisted of running on a treadmill at 60-70% of Vo2max. Supplementation group: According to the literature, the daily supplementation dose for each participant was 50 mg/ml. Training-supplementation group: Exercise and supplements simultaneously Control group: Participants in the control group did not take part in any exercise activities during this period

Main outcome variables
Interleukin 6؛ Interleukin18؛ Interleukin1β؛ TNF-α

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160129026251N4**
Registration date: **2019-02-02, 1397/11/13**
Registration timing: **retrospective**

Last update: **2019-02-02, 1397/11/13**
Update count: **0**

Registration date
2019-02-02, 1397/11/13

Registrant information

Name
Iman Zakavi

Name of organization / entity
Abadan Medical Sciences School

Country
Iran (Islamic Republic of)

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+98 916 814 3051

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2015-09-23, 1394/07/01

Expected recruitment end date
2016-01-21, 1394/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Anti Inflammatory Properties of Combined Aquatic Extract of Ferulago Angulata Boiss with Aerobic Exercise on Pro Inflammatory Indices in Obese Males

Public title
Effect of Exercise and Supplementation on Pro Inflammatory Cytokines

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Male gender BMI higher than 30 Men aged 30 to 40 years

Exclusion criteria:
Having a history of a specific illness Taking cigarettes and drugs Taking medicine and supplement

Age
From **30 years** old to **40 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Following the screening process, 40 obese Men will be selected randomly and randomly divided into 4 groups.Subjects are randomly selected to have a BMI greater than 30. Randomization tools include random digits table and spss software version 24.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Ethics committee of Abadan University of Medical Sciences, Vice chancellor for research, Opposite International Airport Jami Abadan, Flying field, Abadan City, Khouzestan.

City
Abadan

Province
Khouzestan

Postal code
6395116214

Approval date
2015-05-20, 1394/02/30

Ethics committee reference number
IR.ABADANUMS.REC.1394.10

Health conditions studied

1

Description of health condition studied
Obesity

ICD-10 code
E66

ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
Interleukin 6

Timepoint
Before intervention, 3 months after intervention

Method of measurement
pg/ml- ELISA method

2

Description
Interleukin18

Timepoint
Before intervention, 3 months after intervention

Method of measurement
pg/ml- ELISA method

3

Description
Interleukin1β

Timepoint
Before intervention, 3 months after intervention

Method of measurement
pg/ml- ELISA method

4

Description
TNF-α

Timepoint
Before intervention, 3 months after intervention

Method of measurement
pg/ml- ELISA method

Secondary outcomes

1

Description
Weight
Timepoint
Before intervention, 3 months after intervention
Method of measurement
kg, In body Device

2

Description
Body Mass Index
Timepoint
Before intervention, 3 months after intervention
Method of measurement
kg/m2-In Body device

3

Description
fat percentage
Timepoint
Before intervention, 3 months after intervention
Method of measurement
% Percentage, In Body Device

4

Description
Waist -to-Hip Ratio
Timepoint
Before intervention, 3 months after intervention
Method of measurement
cm, Meter

5

Description
Maximal Oxygen Consumption
Timepoint
Before intervention, 3 months after intervention
Method of measurement
ml/kg/min---By Rockport 1-mile walk test

Intervention groups

1

Description
Intervention group 1:The aerobic training consisted of running on a treadmill at 60-70% of Vo2max. Each training session included a 5-10 minutes of warm-up and cool down. After four weeks, maximal HR was measured once more and the training intensity of 60-70% of Vo2max was adjusted accordingly
Category
Other

2

Description
Intervention group 2:Leaves form Ferulagoangulata were grounded using an electric mill and the powder was then bolted to separate the big particles. To make the Ferulagoangulata extract 8 grams of the powder was wrapped in a piece of two-layer tiffany cloth and then was put in a flask containing 100 mm of distilled, sterilized water. The container was then put in a shaker for 24 hours at room temperature. The extract was then passed through a filter under the laboratory's hood. The produced extract was then stored at 4ºc before consumption. According to the literature, the daily supplementation dose for each participant was 50 mg/ml.Participants in the supplementation group did not take part in any exercise activities during this period and were only involved in their daily routine activities
Category
Other

3

Description
Intervention group 3:The aerobic training consisted of running on a treadmill at 60-70% of Vo2max. Each training session included a 5-10 minutes of warm-up and cool down. After four weeks, maximal HR was measured once more and the training intensity of 60-70% of Vo2max was adjusted accordingly. Leaves form Ferulagoangulata were grounded using an electric mill and the powder was then bolted to separate the big particles. To make the Ferulagoangulata extract 8 grams of the powder was wrapped in a piece of two-layer tiffany cloth and then was put in a flask containing 100 mm of distilled, sterilized water. The container was then put in a shaker for 24 hours at room temperature. The extract was then passed through a filter under the laboratory's hood. The produced extract was then stored at 4ºc before consumption. According to the literature, the daily supplementation dose for each participant was 50 mg/ml. In this group exercise and supplements will be done simultaneously.
Category
Other

4

Description
Control group: Participants in the control group did not take part in any exercise activities during this period and were only involved in their daily routine activities
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Tabatabai Hospital
Full name of responsible person

Amin Delavari
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Shahid Tabatabai HospitaL, Ghale Kamisi St., Baghmalek City, Kouzestan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
DR mohamad mahboobi
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Vice chancellor for research, Abadan University of Medical Sciences, Opposite International Airport Jami Abadan, Flying field, Abadan city, Khouzestan, Iran
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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
Abadan 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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Iman Zakavi
Position
Ph.D. Specialist
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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable