

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 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 *Ferulago angulata* consumption on serum levels of IL-6, IL-18, IL-1 β 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: Interleukin1 β : 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)

Phone

+98 916 814 3051

Email address

zakavi.i@ajums.ac.ir

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

Interleukin1 β

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 4°C 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 4°C 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
Street address
Shahid Tabatabai Hospital, Ghale Kamisi St.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Abadan University of Medical Sciences

Full name of responsible person

DR mohamad mahboobi

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Phone

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Email

research.abadan@chmail.ir

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**

Abadan University of Medical Sciences

Full name of responsible person

Iman Zakavi

Position

Ph.D. Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for updating data

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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