# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 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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**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**
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**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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## Sponsors / Funding sources

### 1

**Sponsor**
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DR mohamad mahboobi
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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**
Abadan University of Medical Sciences
**Full name of responsible person**
Iman Zakavi
**Position**
Ph.D. Specialist
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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