Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Effects of Saffron (Crocus sativus L.) supplementation and Combined Training on Physiological Regulators in obese men with T2DM

Protocol summary

Study aim
The effect of saffron supplementation and Combined Training on Physiological and biochemical markers in obese men with type 2 diabetes

Design
volunteers first register and then subjects selected purposefully based on inclusion criteria, and randomly divided into Four groups of Combined Training, saffron, Combined Training + saffron and control.

Settings and conduct
Subjects in Combined Training groups and saffron + Combined Training groups performed the Combined Training protocol for twelve weeks (3 days per week). also Subjects in the saffron and Combined Training + saffron groups consumed one tablet (100 mg) of saffron daily for twelve weeks. All exercises were performed at a gym, also Blood samples were evaluated before and after interventions in the laboratory.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 30-50 years, BMI > 30 kg/m2, fasting blood glucose ≥ 126 mg/dL, HbA1C ≥ 6.5%. Exclusion criteria: use insulin, having cardiovascular diseases, musculoskeletal disorders, liver disease, kidney disease, and thyroid dysfunction. having regular physical activity in the past year, Not taking dietary supplements, Sensitivity to saffron.

Intervention groups
Four groups of Combined Training, saffron, Combined Training + saffron and control.

Main outcome variables
Insulin, testosterone, Nitric oxide, hs-CRP, TNF-α, IL-6, IL-10, adiponectin, leptin, Chemerin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190731044398N4**
Registration date: **2020-07-25, 1399/05/04**
Registration timing: **retrospective**

Last update: **2020-07-25, 1399/05/04**
Update count: **0**

Registration date
2020-07-25, 1399/05/04

Registrant information

Name
Babak Hooshmand Moghadam

Name of organization / entity
Ferdowsi University of Mashhad

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-30, 1399/03/10

Expected recruitment end date
2020-06-14, 1399/03/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of Saffron (Crocus sativus L.) supplementation and Combined Training on Physiological Regulators in obese men with T2DM

Public title

Effects of Saffron (Crocus sativus L.) supplementation and Combined Training in obese men with T2DM

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

age 30-50 years BMI > 30 kg/m2 fasting blood glucose ≥ 126 mg/dL HbA1C ≥ 6.5%

Exclusion criteria:

use insulin having cardiovascular diseases, musculoskeletal disorders, liver disease, kidney disease, and thyroid dysfunction having regular physical activity in the past year Not taking dietary supplements Sensitivity to saffron

Age

From **30 years** old to **50 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize, simple randomization method with random number Table method was used. This table contains a bunch of numbers that are randomly drawn in the form of a table without a specific pattern and order. The numbers directions(Left, right, up, down) were first determined by the researcher to read the numbers and then the numbers were considered for different research groups. In the next step, the researcher randomly placed on one of the numbers and moved in the present direction and recorded the numbers for that direction in the target group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this research, participants are unaware of the group assigned to themselves and other participants. experts in laboratory analysis are also unaware of the type of intervention and the participating groups.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ferdowsi University of Mashhad

Street address

Ferdowsi University of Mashhad, Azadi Sq., Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948974

Approval date

2019-11-13, 1398/08/22

Ethics committee reference number

IR.UM.REC.1399.009

Health conditions studied

1

Description of health condition studied

type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

2

Description of health condition studied

obesity

ICD-10 code

E66

ICD-10 code description

obesity

Primary outcomes

1

Description

Fasting insulin

Timepoint

Before and after intervention

Method of measurement

Autoanalyzer kit

2

Description

Serum levels of testosterone

Timepoint

Before and after intervention

Method of measurement

Blood sampling and using ELISA method

3

Description

Serum levels of Nitric oxide

Timepoint
Before and after intervention
Method of measurement
Blood sampling and using ELISA method

4

Description
Serum levels of hs-CRP
Timepoint
Before and after intervention
Method of measurement
Blood sampling and using ELISA method

5

Description
Serum levels of TNF-α
Timepoint
Before and after intervention
Method of measurement
Blood sampling and using ELISA method

6

Description
Serum levels of IL-6
Timepoint
Before and after intervention
Method of measurement
Blood sampling and using ELISA method

7

Description
Serum levels of IL-10
Timepoint
Before and after intervention
Method of measurement
Blood sampling and using ELISA method

8

Description
Serum levels of adiponectin
Timepoint
Before and after intervention
Method of measurement
Blood sampling and using ELISA method

9

Description
Serum levels of leptin
Timepoint
Before and after intervention
Method of measurement
Blood sampling and using ELISA method

10

Description
Serum levels of Chemerin
Timepoint
Before and after intervention
Method of measurement
Blood sampling and using ELISA method

Secondary outcomes

1

Description
fat mass
Timepoint
Before and after intervention
Method of measurement
bioelectrical impedance device

2

Description
fat free mass
Timepoint
Before and after intervention
Method of measurement
bioelectrical impedance device

3

Description
Dietary intake
Timepoint
Before and after intervention
Method of measurement
Food record questionnaire

Intervention groups

1

Description
Intervention group: The training group performed 12 weeks and each week 3 sessions of combined training (Resistance training, Aerobic training). Resistance training (Three sets / six exercises / 60-90-second rest between each set/ 90-120-second rest between each exercise) which contained leg press, bench press, leg extension, lat pulldown, lying leg curl, and shoulder press. the aerobic training protocol was 1×10 minutes exercise with one minute active rest between the sets.
Category
Prevention

2

Description
Intervention group: The saffron group consumed one pill of 100 mg of saffron for 12 weeks.
Category
Prevention

3

Description
Intervention group: the saffron + training group

performed a combined training program (Resistance training, Aerobic training) for 12 weeks and 3 sessions per week and consumed one pill of 100 mg of saffron daily. Resistance training (Three sets / six exercises / 60-90-second rest between each set/ 90-120-second rest between each exercise) which contained leg press, bench press, leg extension, lat pulldown, lying leg curl, and shoulder press. the aerobic training protocol was 1×10 minutes exercise with one minute active rest between the sets.

Category
Prevention

4

Description
Control group: The control group did not perform combined training and did not consume saffron.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
University of Tehran

Full name of responsible person
Abbas Ali Gaeini

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Faculty of Physical Education and Sport Science of Tehran University, Northern Kargar Ave, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor For Research, Ferdowsi University

Full name of responsible person
amir rashidlamir

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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
Vice Chancellor For Research, Ferdowsi University

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
Ferdowsi University of Mashhad

Full name of responsible person
amir rashidlamir

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiology

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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Publication of protocol study in form of the article and also data publication in the original article. The total potential data can be shared after unidentifiable subjects.
When the data will become available and for how long
6 months after the publication of results
To whom data/document is available
All researchers who have access to clinical trials databases.
Under which criteria data/document could be used
The only way for using the data is after the publication of the article in the indexed ISI journal.
From where data/document is obtainable
Via database websites such as PubMed and google scholar and via email address: b.hooshmand.m@gmail.com
What processes are involved for a request to access data/document
The original article reaches the requestor by email within a maximum of one week.
Comments