

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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)

Phone

+98 51 3881 0540

Email address

babak.hooshmand@mail.um.ac.ir

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 1x10 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

Street address

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

City

Tehran

Province

Tehran

Postal code

1417614418

Phone

+98 21 8835 1730

Email

aagaini@ut.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor For Research, Ferdowsi University

Full name of responsible person

amir rashidlamir

Street address

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948974

Phone

+98 51 3880 5000

Email

amir.rashidlamir@um.ac.ir

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

Street address

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948974

Phone

+98 51 3880 5000

Email

amir.rashidlamir@um.ac.ir

Person responsible for scientific 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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Postal code

9177948974

Phone

+98 51 3880 5000

Email

amir.rashidlamir@um.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Ferdowsi University of Mashhad

Full name of responsible person

Babak Hooshmand Hoghadam

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Physiology

Street address

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948974

Phone

+98 51 3880 5000

Email

b.hooshmand.m@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

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