# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## The Effect of aerobic and Resistance Training with Saffron Aqua Extract on Glutathione peroxidase and Malondialdehyde in Men with Type 2 Diabetes

## Protocol summary

**Study aim**
Assessing the effect aerobic and resistance training with saffron aqua extract on glutathione peroxidase and malondialdehyde in men with Type 2 Diabetes

**Design**
In this research, 36 men with Type 2 Diabetes voluntarily will be selected as the study population and randomly divide into six groups: Aerobic training , Resistance training, Resistance training combine with Saffron supplement, Aerobic training group combine with Saffron supplement and Control groups.

**Settings and conduct**
The present study is a semi-experimental study among the men with Type 2 Diabetes in Rasht. The subjects will participate in the exercise training program and saffron supplement for 8 weeks. Blood sampling is performed after 12 hours of fasting and before and after eight weeks of exercise training.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Have age ranges 35-48 years, not have regular exercise training during last year Exclusion criteria: have cardiovascular and orthopedic disease.

**Intervention groups**
Resistance training group: eight weeks, three times per week with intensity 65-70% 1RM Aerobic training group: eight weeks, three times per week with intensity 55-70 % Maximum heart rate Resistance training combine with Saffron supplement: Similar to aerobic training group combine with daily consumption of 3 mg Saffron (before exercise training with 8 week) Aerobic training group combine with Saffron supplement: Similar to aerobic training group combine with daily consumption of 3 mg Saffron (before exercise training with 8 week Control group: consumption of daily 3 mg of saffron supplement as a placebo Control group: Without intervention

**Main outcome variables**
glutathione peroxidase and malondialdehyde

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20150531022498N21**
Registration date: **2018-04-19, 1397/01/30**
Registration timing: **retrospective**

Last update: **2018-04-19, 1397/01/30**
Update count: **0**

**Registration date**
2018-04-19, 1397/01/30

**Registrant information**

**Name**
Ramin Shabani

**Name of organization / entity**
Islamic Azad University

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2016-04-19, 1395/01/31

**Expected recruitment end date**
2016-06-20, 1395/03/31

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**

empty

**Scientific title**
The Effect of aerobic and Resistance Training with Saffron Aqua Extract on Glutathione peroxidase and Malondialdehyde in Men with Type 2 Diabetes

**Public title**
The Effect of aerobic and Resistance Training with Saffron Aqua Extract in Men with Type 2
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Have age ranges 35-48 years with Type 2 Diabetes Be man No regular exercise
**Exclusion criteria:**
have cardiovascular and orthopedic disorders
**Age**
From **35 years** old to **48 years** old
**Gender**
Male

**Phase**
2-3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **36**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Assigning samples using Simple random-lottery method
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Islamic Azad University Rasht Branch
**Street address**
Islamic Azad University Rasht Branch, Taleshan Bridge, Rasht
**City**
Rasht
**Province**
Guilan
**Postal code**
4147654919
**Approval date**
2018-02-09, 1396/11/20
**Ethics committee reference number**
IR.IAU.RASHT.REC.1396.58

## Health conditions studied

### 1

**Description of health condition studied**
Type 2 diabetes
**ICD-10 code**
E11
**ICD-10 code description**
Type 2 diabetes mellitus

## Primary outcomes

### 1

**Description**
Malondialdehyde
**Timepoint**
Before and after the end of interventions
**Method of measurement**
Serum level by ELISA method(n mol/ ml)

### 2

**Description**
Glutathione peroxidase
**Timepoint**
Before and after the end of interventions
**Method of measurement**
Serum level by ELISA method (U/l)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Aerobic training group: eight weeks, three times per week with intensity 55-70 % Maximum heart rate
**Category**
Prevention

### 2

**Description**
Intervention group: Resistance training group: eight weeks, three times per week with intensity 65-70% 1RM
**Category**
Prevention

### 3

**Description**

Intervention group: Aerobic training combine with Saffron supplement: Similar to aerobic training group combine with daily consumption of 3 mg Saffron (before exercise training with 8 week)

**Category**

Prevention

**4**

**Description**

Intervention group: Resistance training combine with Saffron supplement: Similar to resistance training group combine with Saffron supplement

**Category**

Prevention

**5**

**Description**

Control group: consumption of daily 3 mg of saffron supplement as a placebo

**Category**

Prevention

**6**

**Description**

Control group: Without intervention

**Category**

Lifestyle

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Vali Asr Hospital in Rasht

**Full name of responsible person**

Vahid Aghajani

**Street address**

Islamic Azad University Rasht Branch, Taleshan Bridge, Rasht

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Ali Delpasand

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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**

Islamic Azad 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**

Islamic Azad University

**Full name of responsible person**

Vahid Aghajani

**Position**

MA

**Latest degree**

Master

**Other areas of specialty/work**

Exercise physiology

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## Person responsible for scientific inquiries

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**Position**
Associate professore

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## Person responsible for updating data

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**Other areas of specialty/work**
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available