

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 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)

##### Phone

+98 13 3375 2715

##### Email address

shabani@iaurasht.ac.ir

##### 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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**Phone**

+98 13 3342 2153

**Email**

marzieh.nazari.v@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Ali Delpasand

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shabani\_msn@yahoo.com

**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

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr Ramin Shabani

**Position**

Associate professore

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Exercise physiology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Marzieh Nazari

**Position**

Ph.D student

**Latest degree**

Master

**Other areas of specialty/work**

Exercise physiology

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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