

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### The effect of a high-intensity interval training and aloe vera supplementation on some plasma adipokines in type 2 diabetic

#### Protocol summary

##### Study aim

Response of adipokines and oxidative markers and to a period of high-intensity exercise with aloe vera in type 2 diabetic men

##### Design

semi experimental research and clinical trial for control groups, exercise and blind one-way supplementation Random on 44 patients who used the Rand function of Excel software for randomization.

##### Settings and conduct

Place of research in Amol city, Takhti Sports Club. At the beginning and end of the protocol, anthropometric characteristics will be measured. Experimental groups complete a 12-week exercise and supplementation program. Subjects in the supplement group will receive one aloe vera capsule containing 100 mg of aloe vera gel powder in morning

##### Participants/Inclusion and exclusion criteria

Type 2 diabetes (people with a history of more than twice the fasting glucose above 126 mg / dL with HbA1c above 6.5% ), no history of regular exercise for the past six months, and no intake and each of the drugs that reduce blood pressure and Lipid use was excluded from this study. Exclusion criteria included a history of serious diabetic complications (such as proliferative diabetic retinopathy), fasting glucose above 270 mg / dL, indication for insulin therapy, malaise Hereditary absorption of glucose and galactose or renal glycosuria.

##### Intervention groups

Four groups (11 people in each group) including control groups, aloe vera supplement group (each capsule containing 100 mg of aloe vera gel powder and each subject one capsule in the morning immediately after waking up and one capsule after dinner Will receive), a high-intensity intermittent exercise group (including fast pedaling for 8 seconds (about 80% of maximum heart rate (HRmax)) followed by gentle pedaling (20-30 rpm) for 12 seconds And high-intensity interval training group - aloe vera supplement

#### Main outcome variables

METRNL,TAC,Glutathione peroxidase, Superoxide dismutase,Malone di aldehyde, cathepsin

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140415017288N8**

Registration date: **2021-09-07, 1400/06/16**

Registration timing: **prospective**

Last update: **2021-09-07, 1400/06/16**

Update count: **0**

##### Registration date

2021-09-07, 1400/06/16

##### Registrant information

##### Name

Ahmad Abdi

##### Name of organization / entity

Ayatollah Amoli Branch, Islamic Azad University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 4321 7126

##### Email address

a.abdi@iauamol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-16, 1400/08/25

##### Expected recruitment end date

2022-01-15, 1400/10/25

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of a high-intensity interval training and aloe vera supplementation on some plasma adipokines in type 2 diabetic

**Public title**

high-intensity interval training and aloe vera supplementation

**Purpose**

Health service research

**Inclusion/Exclusion criteria****Inclusion criteria:**

Type 2 diabetes (people with a history of more than twice the fasting glucose above 126 mg / dL with HbA1c above 6.5% and under the supervision of a physician at the time of the study) . Subjects were asked to complete a questionnaire of readiness to start sports. Lack of cardiovascular Lack of musculoskeletal Lack of metabolic diseases limited exercise lack of high blood pressure lack of a history of regular exercise during the past six months lack of insulin

**Exclusion criteria:**

Use of drugs that lower blood pressure and blood lipids  
Exclusion criteria included a history of serious diabetic complications (such as proliferative diabetic retinopathy, stage 3 or subsequent overt nephropathy, diabetic ketoacidosis or severe diabetic neuropathy) fasting glucose above 270 mg / dL malaise Hereditary absorption of glucose and galactose or renal glycosuria

**Age**

From **25 years** old to **40 years** old

**Gender**

Male

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **44**

More than 1 sample in each individual

Number of samples in each individual: **8**

type 2 diabetic men

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this research, subjects are selected Simple randomization by random allocation rule. After determining the sample size, they will be equally divided into 4groups (1- Control, 2- Exercise, 3- supplementation and 4- Exercise + supplementation ). Using the lottery method, the names of the subjects are written on separate papers and placed in a container, then the names of the subjects are randomly taken out and placed in the intervention groups or placebo, respectively.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Each capsule will contain 100 mg of aloe vera gel powder, and each subject will receive one capsule in the morning immediately after waking up and one capsule after dinner, and the control and exercise groups will receive the same amount of placebo. Starch is used as a placebo.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Marvdasht Branch of Azad University

**Street address**

Three kilometers of Persepolis Boulevard, Islamic Azad University of Marvdasht

**City**

Marvdasht

**Province**

Fars

**Postal code**

73711-13119

**Approval date**

2020-09-13, 1399/06/23

**Ethics committee reference number**

IR.IAU.M.REC.1399.037

**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**

Metrenal

**Timepoint**

Before and after the protocol

**Method of measurement**

Biochemical and laboratory methods

## 2

### **Description**

Catspin

### **Timepoint**

Before and after the protocol

### **Method of measurement**

Biochemical and laboratory methods

## 3

### **Description**

Total Antioxidant Capacity

### **Timepoint**

Before and after the protocol

### **Method of measurement**

Biochemical and laboratory methods

## 4

### **Description**

Malondialdehyde

### **Timepoint**

Before and after the protocol

### **Method of measurement**

Biochemical and laboratory methods

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Control group: (in this group we have not any intervention during 12 weeks, and will consider this group as placebo)

#### **Category**

Placebo

### 2

#### **Description**

Intervention group: High Intensity Periodic Exercise Group (Training protocol of up to 60 cycles per 20-minute session (including 8 seconds of fast pedaling (about 80% of maximum heart rate (HRmax)) followed by gentle pedaling (20-30 rpm) for 12 seconds , To facilitate acceleration and limit the stagnation of the bicycle wheel, the selected resistance will be very low (almost zero).

#### **Category**

Treatment - Other

### 3

#### **Description**

Intervention group: Aloe vera supplement group Each capsule will contain 100 mg of aloe vera gel powder, and each subject will receive one capsule in the morning immediately after waking up and one capsule after

dinner.

#### **Category**

Treatment - Other

### 4

#### **Description**

Intervention group: High Intensity Periodic Exercise Group - Aloe Vera Supplement (In this group the Simultaneous intervention, aloe vera gel and training, will treat with the same protocol that describe at the previous part).

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Tehran Diabetes Association

##### **Full name of responsible person**

Ahmad Abdi

##### **Street address**

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Islamic Azad University

##### **Full name of responsible person**

AsiehAbbassi Dalooi

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abbasi.dalooi@gmail.com

**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
No  
**Title of funding source**  
Islamic Azad University  
**Proportion provided by this source**  
100  
**Public or private sector**  
Private  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Other

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Ahmad Abdi  
**Position**  
Associate Professor  
**Latest degree**  
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Sport Medicine  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

The report is submitted to the research department of the university. Also published as a paper

### When the data will become available and for how long

Since 2021

### To whom data/document is available

All researchers

### Under which criteria data/document could be used

Citing references

**From where data/document is obtainable**

Scientific bases and Ayatollah Amoli Branch, Islamic Azad University, amol, Iran

**What processes are involved for a request to access data/document**

Maximum one week

**Comments**