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

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
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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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Other areas of specialty/work
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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