Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the effects of combined exercise, whey protein and vitamin D supplementation on insulin resistance in women with diabetes type 2

Protocol summary

Study aim
Regarding the importance of diabetes treatment and patients' quality of life, the aim of this study is to assess the effects of interventions such as excercise and supplementation in patients with diabetes type 2.

Design
A controlled paralleled non_blinded clinical trial

Settings and conduct
Patients with type 2 diabetes referred to Khomam health center are divided into intervention and control groups. There is no blinding. For intervention group, exercise program, water-soluble protein powder and vitamin D are given daily. For control group, patients will be examined at baseline and after 8 weeks without any intervention. Hemoglobin A1C level will be assessed in both groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The duration of diabetes of patients is less than 10 years. Patients do not have complications of diabetes type 2 including nephropathy, neuropathy, and retinopathy. Patients do not use Insulin. Patients do not use supplements. Hemoglobin A1C is less than 10%.
Exclusion criteria: Body Mass Index is more than 40

Intervention groups
Intervention group: Exercise program for 8 weeks which includes aerobic exercise with the intensity of 70% to 50% of maximum heart rate. Exercise is three times a week for 45-60 minutes each time. Twenty grams of water-soluble protein powder of Karen company is given daily to these subjects as well. Two 500- units equivalent to 1000 units of vitamin D of Jalinous company are given daily . Control group: Patients will be examined at baseline and after 8 weeks without any intervention

Main outcome variables
Hemoglobin A1C level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190707044133N1**
Registration date: **2019-08-23, 1398/06/01**
Registration timing: **retrospective**

Last update: **2019-08-23, 1398/06/01**
Update count: **0**

Registration date
2019-08-23, 1398/06/01

Registrant information

Name
Tania Ghaffari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 13 4455 5191

Email address
taniaghafari92@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2015-04-21, 1394/02/01

Expected recruitment end date
2015-09-23, 1394/07/01

Actual recruitment start date
2015-04-21, 1394/02/01

Actual recruitment end date
2015-09-23, 1394/07/01

Trial completion date
2015-09-23, 1394/07/01

Scientific title
Comparing the effects of combined exercise, whey protein and vitamin D supplementation on insulin resistance in women with diabetes type 2

Public title
Effects of combined exercise with supplementation on diabetes
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Duration of diabetes of patients is less than 10 years. Patients do not have complications of diabetes type 2 including nephropathy, neuropathy, and retinopathy. Patients do not use Insulin. Patients do not use supplements. Hemoglobin A1C is less than 10%.
Exclusion criteria:
Body Mass Index is more than 40
Age
From **45 years** old to **60 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **30**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Islamic Azad University
Street address
Taleshan Bridge, Lakan Boulevard, Gaz square
City
Rasht
Province
Guilan
Postal code
۴۱۴۷۶۵۴۹۱۹
Approval date
2016-09-18, 1395/06/28
Ethics committee reference number
IR.IAU.RASHT.REC.1395.12

Health conditions studied

1

Description of health condition studied
Diabetes
ICD-10 code
E08
ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Hemoglobin A1C
Timepoint
before intervention and 8 weeks after intervention
Method of measurement
Enzymatic calorimetric method by bionic kits

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Exercise program for 8 weeks which includes aerobic exercise with the intensity of 70% to 50% of maximum heart rate. Exercise is three times a week for 45-60 minutes each time. Twenty grams of water-soluble protein powder of Karen company is given daily to these subjects as well. Two 500- units equivalent to 1000 units of vitamin D of Jalinous company are given daily .
Category
Lifestyle

2

Description
Control group: Patients will be examined at baseline and after 8 weeks without any intervention
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Health Centers of Khomam
Full name of responsible person
Tania Ghaffari
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Taleshan Bridge, Lakan Boulevard, Gaz square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Mozaffar Mirbargkar
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Taleshan Bridge, Lakan Boulevard, Gaz square
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4147654919
Phone
+98 13 3342 3308
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mir.bargkar.m@gmail.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
Tania Ghaffari
Position
Researcher
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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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
Not applicable