

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 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 exercise 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

taniaghaffari92@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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
Mozaffar Mirbargkar
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4147654919
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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