

# 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

##### Street address

Taleshan Bridge, Lakan Boulevard, Gaz square

##### City

Rasht  
**Province**  
Guilan  
**Postal code**  
۴۱۴۷۶۵۴۹۱۹  
**Phone**  
+98 13 4454 7687  
**Email**  
taniaghafari92@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Mozaffar Mirbargkar  
**Street address**  
Taleshan Bridge, Lakan Boulevard, Gaz square  
**City**  
Rasht  
**Province**  
Guilan  
**Postal code**  
4147654919  
**Phone**  
+98 13 3342 3308  
**Email**  
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**

Nutrition  
**Street address**  
Taleshan Bridge, Lakan Boulevard, Gaz square  
**City**  
Rasht  
**Province**  
Guilan  
**Postal code**  
۴۱۴۷۶۵۴۹۱۹  
**Phone**  
+98 13 4454 7687  
**Email**  
Taniaghafari92@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Tania Ghafari  
**Position**  
Researcher  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nutrition  
**Street address**  
Taleshan Bridge, Lakan Boulevard, Gaz square  
**City**  
Rasht  
**Province**  
Guilan  
**Postal code**  
۴۱۴۷۶۵۴۹۱۹  
**Phone**  
+98 44547687  
**Email**  
taniaghafari92@gmail.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Tania Ghafari  
**Position**  
Researcher  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nutrition  
**Street address**  
Taleshan Bridge, Lakan Boulevard, Gaz square  
**City**  
Rasht  
**Province**  
Guilan  
**Postal code**  
۴۱۴۷۶۵۴۹۱۹

**Phone**

+98 13 4454 7687

**Email**

taniaghafari92@gmail.com

**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