

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Aug 2026

The effect of 8 weeks vitamin D supplementation and water training on serum glycosylated hemoglobin, CRP, insulin resistance and lipid profile in women with type 2 diabetes

Protocol summary

Study aim

The effects of 8 weeks vitamin D supplementation and water exercise on serum glycosylated hemoglobin, CRP, insulin resistance and lipid profile in women with type 2 diabetes

Design

The subjects participated in a briefing session one week before the implementation of the main research protocol. In this session, in addition to explaining the research steps, they signed a written consent to participate in the test. Some anthropometric indices such as height, weight, blood pressure, heart rate, and body mass index (BMI) were measured. The age and medical history of individuals were completed using a questionnaire. To evaluate the diet of the subjects in terms of vitamin D intake and ensure that the diet did not change, a 24-hour recall questionnaire was completed at the beginning and end of the study. Subjects were then randomly divided into four groups

Settings and conduct

Each session was performed from 9 to 10 in the morning for one hour in the shallow part (80 cm) of the pool of Razi University in Kermanshah. The intensity of the exercises was controlled using Borg comparison.

Participants/Inclusion and exclusion criteria

No smoking • No history of cardiovascular disease • Do not have any joint disease • No fear of water • Older women between 40 and 60 years old

Intervention groups

4 groups include: Group 1: Exercise in water (12 people); Group 2: Exercise in water with vitamin D supplementation (12 people); Group 3: Vitamin D supplementation (n = 12); Fourth group: control (12 people) was divided.

Main outcome variables

Glycosylated hemoglobin Reactive protein C Insulin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201223049811N1**

Registration date: **2021-01-12, 1399/10/23**

Registration timing: **retrospective**

Last update: **2021-01-12, 1399/10/23**

Update count: **0**

Registration date

2021-01-12, 1399/10/23

Registrant information

Name

Mohammad Azizi

Name of organization / entity

Razi university

Country

Iran (Islamic Republic of)

Phone

+98 83 3832 4201

Email address

mo.azizi@razi.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

2016-05-04, 1395/02/15

Actual recruitment end date

2016-07-06, 1395/04/16

Trial completion date

2019-07-07, 1398/04/16

Scientific title

The effect of 8 weeks vitamin D supplementation and water training on serum glycosylated hemoglobin, CRP, insulin resistance and lipid profile in women with type 2 diabetes

Public title

The effect of water exercise and vitamin D consumption on the health of diabetics

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Type 2 diabetes non-athlete 40-60 years old women

Exclusion criteria:

Being a smoker Having heart disease Fracture or joint injury

Age

From **40 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **48**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a random number table, all subjects were divided into 4 equal groups. And were randomly assigned to one of the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

None of the groups and researchers were aware of the status of supplementation and training, and an individual in charge of holding training sessions has taken responsibility for this.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Sciences

Street address

The end of the passport street - Nik Farjahan Comple

City

kermanshah

Province

Kermanshah

Postal code

3257970692

Approval date

2018-11-14, 1397/08/23

Ethics committee reference number

IR.KUMS.REC.1397.656

Health conditions studied

1

Description of health condition studied

Diabetes type 2

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Glycosylated hemoglobin

Timepoint

At the beginning of the study and after 8 weeks

Method of measurement

In the blood and by chromatographic method with ion exchange and using Pars kit test was measured.

Secondary outcomes

1

Description

Reactive protein C

Timepoint

At the beginning of the study and after 8 weeks

Method of measurement

In Blood and using ELISA method and kit (ADMA-ELISA, DLD Diagnostika GmbH, Hamburg, Germany) were measured using GC-MS method.

Intervention groups

1

Description

Intervention group: Water exercise group: Do your exercises in water for 8 weeks and every week for three sessions (24 sessions in total) and each session from 9 to 10 in the morning for one hour in the shallow part (120-80 cm)) Razi University swimming pool in Kermanshah.

Category

Prevention

2**Description**

Intervention group: Exercise and vitamin D supplementation: Exactly the same as the exercise group in water, they exercised in water for 8 weeks and also received vitamin D1 per supplement 1 per week for 8 weeks.

Category

Prevention

3**Description**

Intervention group: Vitamin D intake: For 8 weeks and once a week, they received a vitamin D supplement of 1 Perl IU50000.

Category

Prevention

4**Description**

Control group: did not have any indoor or outdoor exercise for 8 weeks. They also did not take any supplements.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Razi University

Full name of responsible person

Mona Salari nia

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Hadi Khalvandi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

20

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**

Persons

Person responsible for general inquiries**Contact****Name of organization / entity**

Razi University

Full name of responsible person

Mona Salari nia

Position

Master of Physiology and Sports Nutrition

Latest degree

Master

Other areas of specialty/work

Physiology and Sports Nutrition

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Person responsible for scientific inquiries**Contact**

Name of organization / entity

Razi University

Full name of responsible person

Mohammad Azizi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise physiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

I haven't decided yet - the release schedule is still unknown

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

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data**Contact****Name of organization / entity**

Razi university

Full name of responsible person

Mohammad Azizi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise physiology

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