

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparing the effectiveness of barley bread enriched with vitamin D microcapsules on serum vitamin D levels, cardiometabolic indices, and kidney function in people with type 2 diabetes.

Protocol summary

Study aim

Determining the effect of consuming barley bread enriched with vitamin D on vitamin D serum level, cardiometabolic indices, and kidney function in people with type 2 diabetes

Design

A clinical trial with an intervention group and control group, with parallel groups, double-blind, randomized, on 130 patients.

Settings and conduct

To enrich barley bread with vitamin D at a dose of 600 international units per gram, we turn this vitamin into microcapsules to increase the stability and solubility of the product; For this purpose, after the production of microcapsules using edible grade wall materials, the size of microcapsules, zeta potential, their solubility, the efficiency of vitamin D encapsulation, the morphology of the capsules and the efficiency of the production process will be evaluated. The place of work is in the food nanotechnology research group of Mashhad Food Science and Industry Research Institute.

Participants/Inclusion and exclusion criteria

Entry conditions include people with type 2 diabetes, and non-entry conditions include the use of drugs that affect vitamin D metabolism; Taking megadose of vitamin D up to 3 months before the start of the intervention or medications that interfere with this vitamin; suffering from endocrine diseases; disorders affecting the metabolism of minerals and vitamin D; They are unusually exposed to sunlight.

Intervention groups

Feeding the intervention group with vitamin D-enriched barley bread and the control group with ordinary barley bread for 4 months

Main outcome variables

Anthropometric indices, cardiometabolic indices, blood pressure, C-reactive protein, blood lipid levels, renal

function, serum vitamin D level.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221203056695N1**

Registration date: **2023-11-08, 1402/08/17**

Registration timing: **retrospective**

Last update: **2023-11-08, 1402/08/17**

Update count: **0**

Registration date

2023-11-08, 1402/08/17

Registrant information

Name

Mohamad Hashemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2409

Email address

hashemimd@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-04, 1400/09/13

Expected recruitment end date

2022-05-01, 1401/02/11

Actual recruitment start date

2022-06-10, 1401/03/20

Actual recruitment end date

2022-09-25, 1401/07/03

Trial completion date

2022-12-06, 1401/09/15

Scientific title

Comparing the effectiveness of barley bread enriched with vitamin D microcapsules on serum vitamin D levels, cardiometabolic indices, and kidney function in people with type 2 diabetes.

Public title

Effect of barley bread fortified with vitamin D in patients with type 2 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

patients with type 2 diabetes

Exclusion criteria:

Pregnancy Taking drugs that affect vitamin D metabolism, such as taking a vitamin D supplement of more than 400 units per day Taking megadoses of vitamin D up to 3 months before the start of the intervention or medications that interfere with this vitamin Suffering from endocrine diseases Disorders affecting the metabolism of minerals and vitamin D Exposure to the sun in an unusual way, such as skin tanning

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **130**

Actual sample size reached: **130**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

The participant and outcome assessor is blinded and assumes that all participants will receive barley bread enriched with microcapsules containing vitamin D, although some will not and will receive barley bread not enriched with vitamin D microcapsules.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

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Qurashi Bldg., Daneshgah St

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Approval date

2016-10-08, 1395/07/17

Ethics committee reference number

IR.MUMS.REC.1395.369

Health conditions studied**1****Description of health condition studied**

Type 2 diabetes

ICD-10 code

E11.8

ICD-10 code description

Type 2 diabetes mellitus with unspecified complications

Primary outcomes**1****Description**

Anthropometric indicators

Timepoint

Evaluation of the anthropometric indicators of people before the start of the study and after the end of the intervention.

Method of measurement

Body Analyzer

2**Description**

Cardiometabolic indicators

Timepoint

Evaluations related to vitamin D serum level, cardiometabolic indicators, and kidney function at the beginning of the study and the end of the intervention

Method of measurement

blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Feeding the intervention group with vitamin D-enriched barley bread for 4 months

Category

Placebo

2

Description

Control group: Feeding the control group with ordinary barley bread

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical School

Full name of responsible person

Dr. Mohsen Nemati

Street address

The east door of the university campus, Azadi Sq.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayor Mobarhan

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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

Mashhad University of Medical Sciences

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

Mashhad University of Medical Sciences

Full name of responsible person

Dr.Mohamad Hashemi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

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Mohamad Hashemi

Position

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Ph.D.

Other areas of specialty/work

Food safety and Health

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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

According to the discretion of the project managers, no decision has been taken to publish the patients' information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

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

Mashhad University of Medical Sciences

Full name of responsible person

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Assistant professor

Latest degree

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