Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Effect of synbiotic and/or vitamin D on intestinal microbiome and its relationship with muscle strength, function and body composition in overweight or obese middle-aged women.

Protocol summary

Study aim

Determining the effect of synbiotic and/or vitamin D on intestinal microbiome and its relationship with muscle strength, function and body composition in overweight or obese middle-aged women

Design

RCT design. Eligible people from the staff of Shiraz university of medical sciences will enter the study. 88 people will randomly divide into 4 groups (vitamin D, synbiotic, vitamin D and synbiotic, placebo) based on permuted block randomization.

Settings and conduct

Eligible women from Shiraz University of Medical Sciences staff will enroll in the study and will receive 1 vitamin D supplement (or placebo) weekly and 1 synbiotic supplement (or placebo) daily for 8 weeks. Anthropometric variables (weight, height, body composition), strength and functional variables (handgrip strength and knee extension and TGUG test), intestinal microbiome and food intake will be measured at the beginning and end of the study. Double blind study (Participants and researcher).

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Overweight and obese women aged 40-55 years 2. Not being menopaused. 3. Body mass index higher than 25 kg/m2 4. Willingness to participate Exclusion criteria: 1. Taking vitamin D supplements during the last 2-3 months, either orally or by injection 2. Consumption of synbiotic, probiotic and prebiotic supplements during the last 2-3 months 3. Having chronic diseases such as diabetes, CVD, liver and kidney disorders, uncontrolled blood pressure, etc. 4. Using vitamins, minerals, omega 3 or fish oil supplement 5. Use of antibiotics during the last three weeks 6. Following a special diet

Intervention groups

1: Vitamin D supplement and synbiotic placebo 2: Vitamin D placebo and synbiotic supplement 3: Vitamin D and a synbiotic supplement 4: Vitamin D placebo and synbiotic placebo

Main outcome variables

Intestinal microbiome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090822002365N25**
Registration date: **2021-03-03, 1399/12/13**
Registration timing: **prospective**

Last update: **2021-03-03, 1399/12/13**
Update count: **0**

Registration date

2021-03-03, 1399/12/13

Registrant information

Name

Mohammad Reza Vafa

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4734

Email address

vafa.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of synbiotic and/or vitamin D on intestinal microbiome and its relationship with muscle strength, function and body composition in overweight or obese middle-aged women.

Public title

Effect of synbiotic with or without vitamin D on intestinal microbiome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Overweight and obese women aged 40-55 years Not being menopaused Body mass index higher than 25 kg/m2 Willingness to participate in the study

Exclusion criteria:

Vitamin D intake during the last 2-3 months, either orally or by injection Taking supplements of synbiotics, probiotics and prebiotics during the last 2-3 months Having chronic diseases such as diabetes, cardiovascular disease, uncontrolled blood pressure, liver and kidney disorders, etc. Supplements intake containing vitamins, minerals and omega-3 or fish oil Antibiotic intake during the last three weeks Following a special diet Using steroidal and non-steroidal anti-inflammatory drugs, anticonvulsants, anti-cholesterol drugs, antacids, diuretics and and laxatives over the past two months Using any medications that affect weight over the past two months (such as medications that affect carbohydrate, protein or fat metabolism, and medications that reduce or increase appetite or food intake).

Age

From **40 years** old to **55 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomized allocation performing, permuted block randomization will be used by quadrilateral blocks. According to the sample size of 88 subjects, 22 blocks will be generated using the online site (www.sealedenvelope.com). In order to allocation concealment in the randomized process, unique codes will be used on the drug boxes that is generated by the software. Participants will be entered into study based on the produced sequence. The drug packets will be allocated to the individual with code on them. Therefore, participants will be unaware of the type of intervention that will receive, as well as the random sequence which will be hidden and unpredictable.

Blinding (investigator's opinion)

Double blinded

Blinding description

For blinding, a person who will not be involved in study protocol will create the randomization list assigning participants to the vitamin D, synbiotic, co-supplementation or the placebo group. Vitamin D, synbiotic, and placebo tablets will be placed into identical containers and all investigators, and participants will be blinded to the random assignments.

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Tehran, Hemmat Highway next to Milad Tower, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2021-01-31, 1399/11/12

Ethics committee reference number

IR.IUMS.REC.1399.1177

Health conditions studied

1

Description of health condition studied

overweight or obese middle-aged women

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description
Intestinal microbiome
Timepoint
Intestinal microbiome assessment at the beginning of the study and after the intervention (end of week 8)
Method of measurement
Real-Time PCR TaqMan method

Secondary outcomes

1

Description
Muscle strength
Timepoint
At the beginning of the study and after the intervention (end of week 8)
Method of measurement
handgrip strength and knee extension

2

Description
Muscle function
Timepoint
At the beginning of the study and after the intervention (end of week 8)
Method of measurement
TGUG test

3

Description
Body composition
Timepoint
At the beginning of the study and after the intervention (end of week 8)
Method of measurement
multi-frequency Bioelectrical Impedance Analysis (BIA) and InBody S10 analyzer

Intervention groups

1

Description
Intervention group 1: Receiving one capsule of 50,000 IU of vitamin D (Zahravi company) weekly, along with one capsule of synbiotic placebo containing maltodextrin (Zist takhmir company) daily, for 8 weeks.
Category
Treatment - Drugs

2

Description
Intervention group 2: Receiving a 500 mg synbiotic capsule (Zist takhmir Company) daily, along with a vitamin D placebo capsule containing paraffin (Zahravi Company) weekly, for 8 weeks.
Category
Treatment - Drugs

3

Description
Intervention group 3: Receiving one 50,000 IU capsule of Vitamin D (Zahravi Company) weekly, along with receiving one 500 mg synbiotic capsule (Zist takhmir Company) daily, for 8 weeks.
Category
Treatment - Drugs

4

Description
Control group: Receiving a vitamin D placebo capsule containing paraffin (Zahravi Company) weekly, along with one capsule of synbiotic placebo containing maltodextrin (Zist takhmir company) daily, for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz university of medical sciences
Full name of responsible person
mohammad reza vafa
Street address
Department of Nutrition, School of Public Health, Iran University of Medical Sciences, Hemmat Highway, Tehran, Iran
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mohammad reza Vafa
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Vice chancellor for research, Iran 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
Iran University of Medical Sciences

Full name of responsible person
Mohammad reza Vafa

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

A part of the data will be shared, such as primary outcomes.

When the data will become available and for how long

Four months after the publication of the results.

To whom data/document is available

Researchers and students of university.

Under which criteria data/document could be used

Four months after the publication of this study papers, the obtained data will be available to the applicant researchers and students for further analysis.

From where data/document is obtainable

Applicants can be contacted with corresponding author by e-mail or postal address to receive the requested data. Postal address: Nutrition Department, School of health, Iran University of Medical Science, Hemmat Expressway, Tehran Phone Number: 0098 2186704743 E-mail: rezavafa@yahoo.com

What processes are involved for a request to access data/document

Applicants can be contacted with corresponding author by e-mail or postal address to receive the requested data. Postal address: Nutrition Department, School of health, Iran University of Medical Science, Hemmat Expressway, Tehran Phone Number: 0098 2186704743 E-mail: rezavafa@yahoo.com

Comments