

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation of the efficacy of low-fat dairy products fortified with encapsulated vitamin D on on biochemical markers of liver, kidney and cardiovascular system functions

Protocol summary

Study aim

Evaluation of efficacy of low-fat dairy products fortified with Nano-encapsulated vitamin D on biochemical markers in adults aged 18 to 65 in Mashhad

Design

The parallel, double-blinded, and randomised phase 3 clinical trial including control group was conducted on 280 adults.

Settings and conduct

The study is a randomized, double-blind clinical trial (therapist and patient are not aware about type of medicine). fortified low-fat dairy products, containing encapsulated vitamin D (1500IU), will be prepared in reliable dairy factory. 280 adults, who lived in Mashhad, will participate in the trial. In this project, individuals are randomly divided into 2 control group and 2 intervention groups. All of the groups complete general information questionnair including demographic information, history of any diseases, and current treatments before starting the trial. Each control group receive one non-fortified dairy product (milk or yogurt) and in each intervention group, one of the products (milk or yogurt) is fortified with vitamin D. Intervention will be considered for 2.5 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria included aged between 18 to 65; having consent for participation in study Exclusion criteria included Not taking any vitamin D supplements three months before the study; not having Chronic Liver Diseases, Cystic Fibrosis, Crohn's, and Sprue

Intervention groups

Control group receiving non-fortified milk. Intervention group receiving daily milk which is fortified with encapsulated vitamin D (1500 IU). Control group receiving non-fortified yogurt. Intervention group receiving daily yogurt which is fortified with encapsulated vitamin D (1500 IU).

Main outcome variables

Bone density, anthropometric factors, blood pressure, biochemical state, depression, eating habits

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101130005280N27**

Registration date: **2019-03-09, 1397/12/18**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-09, 1397/12/18**

Update count: **0**

Registration date

2019-03-09, 1397/12/18

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Scinces, Ibn-e- Sina Psychiatric Hospital

Country

Iran (Islamic Republic of)

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+98 51 3711 2540

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nejatir2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-21, 1397/09/30

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of low-fat dairy products fortified with encapsulated vitamin D on biochemical markers of liver, kidney and cardiovascular system functions

Public title

Evaluation of vitamin D efficacy on biochemical markers

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

aged between 18 to 65 having full consent for participation in trial

Exclusion criteria:

not taking any vitamin D supplement in the last three months before the trial not having Chronic Liver Diseases, Cystic Fibrosis, Crohn's, and Sprue

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **280**

Randomization (investigator's opinion)

Randomized

Randomization description

280 adults were divided into two groups of intervention and two control groups through stratified block randomization by using the numbered, sealed and stapled envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

According to the double-blind study, blinding is done for participants and researchers for the intervention and control group. The intervention and control groups are quite similar in terms of appearance, taste and smell and only intervention groups will contain 1,500 international units of nano encapsulated vitamin D.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of National Institute for Medical Research Development

Street address

National Institute for Medical Research Development, No 21, Besat Ave, West Dr. Fatemi Ave

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۶۹۳۱۱۱

Approval date

2017-07-15, 1396/04/24

Ethics committee reference number

IR.NIMAD.REC.1396.027

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

Vitamin D Deficiency

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Bone Density

Timepoint

Baseline, 75th day

Method of measurement

BMD Method

2**Description**

Anthropometric factors

Timepoint

Baseline, 75th day

Method of measurement

using standard scales for weight and height measurement

3**Description**

Blood pressure

Timepoint

Baseline, 75th day

Method of measurement

Systolic and diastolic blood pressure measurement

4

Description

Depression

Timepoint

Baseline, 75th day

Method of measurement

Beck depression assessment

5

Description

Eating habits

Timepoint

baseline

Method of measurement

FFQ

6

Description

biochemical state

Timepoint

Baseline, 75th day

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

First control group: 70 adults receive 200 ml of daily non-fortified milk for 2.5 months

Category

Lifestyle

2

Description

Intervention group: 70 adults receive 200 ml daily milk fortified with encapsulated vitamin D (1500 IU), for 2.5 months.

Category

Lifestyle

3

Description

Second control group: 70 adults receive 100 ml of daily non-fortified yogurt for 2.5 months.

Category

Lifestyle

4

Description

Intervention group: 70 adults receive 100 ml daily yogurt fortified with encapsulated vitamin D (1500 IU), for 2.5 months.

Category

Lifestyle

Recruitment centers

1

Recruitment center**Name of recruitment center**

Mashhad Faculty Of Medicine

Full name of responsible person

Majid Ghayour-Mobarhan

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Faculty of Medicine, Azadi Sq.

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

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Full name of responsible person

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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

National Institute for Medical Research Development

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

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Person responsible for general inquiries

Contact

Name of organization / entity
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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

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