Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 adlults, 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 inculded aged between 18 to 65; having consent for participation in study Exclusion criteria inculded 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)

Phone
+98 51 3711 2540

Email address
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 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
Street address
Faculty of Medicine, Azadi Sq.
City
Mashhad
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Razavi Khorasan
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9177948564
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
National Institute for Medical Research Development
Full name of responsible person
Reza Malek Zadeh
Street address
National Institute for Medical Research Development, No 21, Besat Ave, West Dr. Fatemi Ave.
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Tehran
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Phone
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Email
NIMAD@RESEARCH.AC.IR
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

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Payam Sharifan

Position

University student

Latest degree

Medical doctor

Other areas of specialty/work

Nutrition

Street address

Faculty of Medicine, Azadi Sq.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Majid Ghayour-Mobarhan

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Payam Sharifan

Position

University student

Latest degree

Medical doctor

Other areas of specialty/work

Nutrition

Street address

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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