

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of vitamin D supplementation on different aspects of physical and mental health in adolscent girls

Protocol summary

Summary

The present study was conducted to investigate the effect of vitamin D Mega-dose supplementation on various aspects of physical and mental health of adolescent girls in Mashhad and Sabzevar Cities. The study population included 988 adolescent girls that took 9 Pearls of vitamin D during 9 weeks. Each tablet contains 50000IU vitamin D. inclusion criterion included adolescent girls with age of between 12 to 18 years; also exclusion criteria included history of chronic diseases, cancer or using of drugs and supplements. Samples of fasting blood, urine and stool were taken in the morning at baseline and after one week of 9 weeks intervention. Validated questionnaires are used for assessment of other variables. serum levels of vitamin D, inflammatory markers, blood glucose, lipid profile, liver and kidney function tests, demographic information, medical history status, sun exposure, use of sunscreen, anthropometric factors, gastrointestinal micro biome, dietary intakes and dietary patterns, dietary habits, physical activity, sleep disorders, Cognitive abilities, quality of life, feel of pain, blood pressure, depression and aggression, irritable bowel syndrome, menstrual disorder and polymorphisms of genes related to vitamin D were assessed before and after of vitamin D supplementations. The ethical committee of Mashhad University of Medical Sciences approved the study, and informed written consent was obtained from all participants.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201509047117N7**

Registration date: **2015-11-25, 1394/09/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-11-25, 1394/09/04

Registrant information

Name

Majid Ghayour Mobarhan

Name of organization / entity

Mashhad University of Medical Sciences,

Country

Iran (Islamic Republic of)

Phone

+98 51 1822 8573

Email address

ghayourm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences
Vice chancellor for health, Mashhad University of Medical Sciences
Vice chancellor for research, sabzavar University of Medical Sciences
Vice chancellor for health, sabzavar University of Medical Sciences

Expected recruitment start date

2015-01-30, 1393/11/10

Expected recruitment end date

2015-05-31, 1394/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of vitamin D supplementation on different aspects of physical and mental health in adolscent girls

Public title

Effects of vitamin D supplementation on different aspects of health

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: student girls with age of between 12 to 18 years exclusion criteria: chronic disease, cancer, drugs and supplements use

Age

From **12 years** old to **18 years** old

Gender

Female

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **988**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad. Doctoral Crossroads. Mashhad university of medical science

City

mashhad

Postal code

Approval date

2015-02-04, 1393/11/15

Ethics committee reference number

4178418

Health conditions studied

1

Description of health condition studied

irritable bowel syndrome

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

2

Description of health condition studied

depression

ICD-10 code

F32

ICD-10 code description

Depressive episode

3

Description of health condition studied

aggression

ICD-10 code

F39

ICD-10 code description

Unspecified mood [affective] disorder

4

Description of health condition studied

quality of life

ICD-10 code

Z00.4

ICD-10 code description

General psychiatric examination, not elsewhere classified

5

Description of health condition studied

Menstrual pattern

ICD-10 code

N94.9

ICD-10 code description

Unspecified condition associated with female genital organs and menstrual cycle

6

Description of health condition studied

dietary intake and dietary pattern

ICD-10 code

E90

ICD-10 code description

Nutritional and metabolic disorders in diseases classified elsewhere

7

Description of health condition studied

Sleep disorders

ICD-10 code

G47

ICD-10 code description

Sleep disorders

8

Description of health condition studied

Vitamin D deficiency

ICD-10 code

E55

ICD-10 code description

Vitamin D deficiency

9

Description of health condition studied

pain

ICD-10 code

F45.4

ICD-10 code description

Persistent somatoform pain disorder

Primary outcomes

1

Description

serum of vitamin d

Timepoint

Before the intervention, A week after the end of 3 months of intervention

Method of measurement

ECL

2

Description

irritable bowel syndrome

Timepoint

Before the intervention, A week after the end of 3 months of intervention

Method of measurement

Rome 3 questionnaire

3

Description

depression

Timepoint

Before the intervention, A week after the end of 3 months of intervention

Method of measurement

beck questionnaire

4

Description

aggression

Timepoint

Before the intervention, A week after the end of 3 months of intervention

Method of measurement

questionnaire

5

Description

Menstrual pattern

Timepoint

Before the intervention, A week after the end of 3 months of intervention

Method of measurement

questionnaire

6

Description

anthropometric factors

Timepoint

Before the intervention, A week after the end of 3 months of intervention

Method of measurement

anthropometric tools

7

Description

blood pressure

Timepoint

Before the intervention, one week after the end of intervention.

Method of measurement

Barometer

8

Description

lipid profile

Timepoint

Before the intervention, A week after the end of 3 months of intervention

Method of measurement

autoanalyzer

9

Description

Sleep disorders

Timepoint

Before the intervention, A week after the end of 3 months of intervention

Method of measurement

questionnaire

10

Description

dietary intake and dietary pattern

Timepoint

Before the intervention, A week after the end of 3 months of intervention

Method of measurement

FFQ, food record

11

Description

liver function

Timepoint

Before the intervention, A week after the end of 3 months of intervention

Method of measurement

ELISA, autoanalyzer

12

Description

kidney function

Timepoint

Before the intervention, A week after the end of 3 months of intervention

Method of measurement

autoanalyzer

13

Description

fasting blood sugar

Timepoint

Before the intervention, A week after the end of 3 months of intervention

Method of measurement

autoanalyzer

14

Description

pain

Timepoint

Before the intervention, A week after the end of 3 months of intervention

Method of measurement

questionare

15

Description

quality of life

Timepoint

Before the intervention, A week after the end of 3 months of intervention

Method of measurement

questionare

16

Description

inflammatory factors

Timepoint

Before the intervention, A week after the end of 3 months of intervention

Method of measurement

autoanalyzer, ELIZA

17

Description

polymorphism

Timepoint

Before the intervention, A week after the end of 3 months of intervention

Method of measurement

taqman, RFLP

18

Description

gut microbiome

Timepoint

Before the intervention, A week after the end of 3 months of intervention

Method of measurement

test of stool sample

19

Description

physical activity

Timepoint

Before the intervention, A week after the end of 3 months of intervention

Method of measurement

پرسشنامه

20

Description

demographic information

Timepoint

Before the intervention, A week after the end of 3 months of intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

vitamin d, 50000IU, once per ten days for three month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health center of khorasan razavi

Full name of responsible person

Sayyed Saeid Khayyatzadeh

Street address

Department of New Sciences and Technology, Faculty of Medicine, Mashhad University of Medical science, Azadi square, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of mashhad university of

medical science

Full name of responsible person

Keyhan Gonoodi

Street address

Department of New Sciences and Technology, Faculty of Medicine, Mashhad University of Medical science, Azadi square, Mashhad

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research of mashhad university of medical science

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Vice Chancellor for health of mashhad university of medical science

Full name of responsible person

Zahra Abasalti

Street address

Department of New Sciences and Technology, Faculty of Medicine, Mashhad University of Medical science, Azadi square, Mashhad

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for health of mashhad university of medical science

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

3

Sponsor

Name of organization / entity

Sabzevar university of medical science

Full name of responsible person

Mohammad Mohammadzadeh

Street address

sabzevar university of medical science, asadabadi street, sabzevar

City

Sabzevar

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sabzevar university of medical science

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad university of medical science

Full name of responsible person

Sayyed Saeid Khayyatzadeh

Position

Phd student of nutrition

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad university of medical science

Full name of responsible person

Majid Ghayour Mobarhan

Position

professor

Other areas of specialty/work**Street address**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

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

Mashhad university of medical science

Full name of responsible person

Sayyed Saeid Khayyatzadeh

Position

Phd student of nutrition

Other areas of specialty/work**Street address**