Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Clinical trial to evaluate the effect of vitamin D supplements on menstrual pattern, levels of Sexual hormones and sexual function in women with multiple sclerosis

Protocol summary

Study aim

This study aimed to evaluate the effects of vitamin D supplementation on the menstrual patterns, sexual function, and sexual hormones among women with multiple sclerosis

Design

A parallel double-blind clinical trial

Settings and conduct

This double-blind clinical trial study was conducted in Dr. Nabavi Neurology Clinic in Tehran. Patients were randomly divided into intervention and control groups. In the intervention group, tablets containing vitamin D 2000 units were used twice a day for 12 weeks, and in the control group, a placebo containing paraffin was used. The patients were unaware of which group they were placed in, and the person who performed the statistical analysis was also unaware of the intervention and control groups.

Participants/Inclusion and exclusion criteria

The inclusion criteria in this study were married women between the ages of 20 and 40 with multiple sclerosis who had the same treatment regimen and whose vitamin D level was less than 50. If the patients did not want to continue the study or did not take more than one dose of vitamin D, they were excluded from the study.If the patients are in the acute stage of the disease or have comorbidity diseases, they will not be included in the study.

Intervention groups

Participants in the intervention group were given vitamin D (2000 IU, Zahravi Pharmaceutical Co) tablets and were asked to take two daily tablets for twelve consecutive weeks. And in the control group, a placebo containing edible paraffin was used.

Main outcome variables

menstrual pattern, sexual function, and sexual hormones

General information

Reason for update

Due to making and correcting minor changes in the inclusion criteria, study sampling time, and blinding of this research. Also, due to the non-cooperation of the hospitals for sampling, Dr. Nabavi's specialized Neurology clinic was used for sampling.

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061528449N4**
Registration date: **2016-08-29, 1395/06/08**
Registration timing: **prospective**

Last update: **2023-01-13, 1401/10/23**
Update count: **1**

Registration date

2016-08-29, 1395/06/08

Registrant information

Name

simin zarabadipour

Name of organization / entity

Iran university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 218670250300

Email address

zarabadipoor.s@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date
2016-11-20, 1395/08/30
Actual recruitment start date
2017-08-01, 1396/05/10
Actual recruitment end date
2018-02-01, 1396/11/12
Trial completion date
2018-02-19, 1396/11/30

Scientific title
Clinical trial to evaluate the effect of vitamin D supplements on menstrual pattern, levels of Sexual hormones and sexual function in women with multiple sclerosis

Public title
Effect of vitamin D pills on Menstrual pattern, levels of Sexual hormones and Sexual function in women with Multiple sclerosis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Married women between 20 and 40 years of age; Confirmation on diagnosis with MS by neurologist during the past year and Having the same therapeutic regimen No acute or chronic disease other than multiple sclerosis No record of disease associated with vitamin D malabsorption (constipation, diarrhea, celiac sprue, short bowel syndrome, and cystic fibrosis) No suffering the husband of chronic diseases and mental illness A minimum of one sexual intercourse in a month The vitamin D serum level of lower than 50 (ng/mL) No record of vitamin D supplementations There is no special diet and be omnivorous The expanded disability status score of lower than 4 no exposure to the severe crisis since the death of someone close to 3 months Not using hormonal contraception at least in the last 3 months; No pregnancy and lactation and does not plan to become pregnant in the last 3 months
Exclusion criteria:
reluctant to continue the study Aggravation of the disease during the study Accurring of pregnancy during the study Facing a critical factor causing such death of a family member or hospitalization in the last 3 months No using regular consumption of vitamin D and avoiding the use of more than one dose during the study; Appearing serious complications that require neurological intervention
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **68**
Actual sample size reached: **62**

Randomization (investigator's opinion)
Randomized
Randomization description
Eligible Participants were consecutively recruited and randomly allocated to an intervention and a control group. For randomization, a table of random numbers from 1 to 200 was generated and then, each new patient recruited to the study was asked to randomly select a number between 1 and 200. She would be allocated to the intervention group if she selected a three-digit odd number, while she would be allocated to the control group if she selected a two-digit even number. Then, selected numbers were removed from the table. If the patient selected any other numbers, she would be asked to select another number until she can pick out either a three-digit odd number or a two-digit even number
Blinding (investigator's opinion)
Double blinded
Blinding description
This was a double-blind study in which neither participants nor statistical analyst was aware of the group allocation. For blinding, participants were not provided with information about the packet content of the tablets. Moreover, they were visited individually and were unaware of the tablets provided to other participants. Vitamin D and placebo tablets used in this study were produced by Zahravi Pharmaceutical Company, Tabriz, Iran. Placebo tablets contain edible paraffin.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
University of Medical Sciences Iran, school of Nursing and Midwifery
Street address
Yasemi Rashid Street, valiasr street, tehran School of Nursing and Midwifery
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2016-05-28, 1395/03/08
Ethics committee reference number
IR.IUMS.REC. 1395.9311373017

Health conditions studied

1

Description of health condition studied
Multiple sclerosis
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Serum levels of 25 hydroxy vitamin D3
Timepoint
The patients' serum 25 hydroxy vitamin D3 levels measured twice (once before and once after the last day of the intervention)
Method of measurement
Blood sampling

2

Description
Levels of Sexual hormones
Timepoint
Patients are tested twice for Levels of Sexualhormones(Estrogen andTestosterone)(One day before the first day of training–one day after the final day training course).
Method of measurement
Blood sampling

Secondary outcomes

1

Description
Menstrual pattern
Timepoint
Patients are tested twice for Menstrual pattern. (One day before the first day of training–one day after the final day training course).
Method of measurement
Questionnaire

2

Description
Sexual function
Timepoint
Patients are tested twice for Sexual function . (One day before the first day of training–one day after the final day training course).
Method of measurement
Questionnaire

Intervention groups

1

Description
In the intervention group using transparent pills of 25 hydroxy vitamin D 3
Category
Placebo

2

Description
In the control group using placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr.Nabavi specialized clinic for neurology
Full name of responsible person
Simin zarabadipour
Street address
Mulla Sadra - between Sheikh Bahai and Chamran - No. 218 - Arya Doctors Complex - 4th floor - Unit 14
City
Tehran
Province
Tehran
Postal code
3414719395
Phone
+98 21 8862 2940
Email
zarabadipours@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Iran University of Medical Sciences
Full name of responsible person
Morteza Naserbakht
Street address
Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 86701
Email

info@iums.ac.ir

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, 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

Simin zarabadipour

Position

MSc student of midwifery

Latest degree

Bachelor

Other areas of specialty/work

Reproductive Health

Street address

Tehran, pasdaran Street, rastvan Street

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 28 3367 5101

Fax

Email

zarabadipours@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

University of Medical Sciences Iran, school of Nursing and Midwifery

Full name of responsible person

Leila Amini

Position

PhD in Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

School of Nursing and Midwifery, Yasemi Rashid Street,Valiasr Street, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 214365181500

Fax

Email

Amini.L@iums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

University of Medical Sciences Iran, school of Nursing and Midwifery

Full name of responsible person

Simin zarabadipour

Position

MSc Student Of Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Reproductive Health

Street address

Rastvan Street, Pasdaran Street, Tehran

City

Tehran

Province

Tehran

Postal code

3414719395

Phone

+98 21 86701

Fax

Email

zarabadipours@yahoo.com

Web page address

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

Not applicable

Title and more details about the data/document

If there is a need to conduct secondary studies or other researchers need the data, the data file, which has been anonymized and includes all the variables measured in this research, will be provided.

When the data will become available and for how long

One year after the results are published

To whom data/document is available

Data for all academic researchers or industrial research centers

Under which criteria data/document could be used

If there is a need to do additional studies or secondary studies

From where data/document is obtainable

If you need to receive data, contact Ms. Zarabadipour :00989127837998

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

Provide the reason for the request and the person or institution that needs this data

Comments