Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effect of vitamin D, vitamin E and ginger on the severity of primary dysmenorrhea among students

Protocol summary

Study aim
The purpose of this study was to compare the effects of vitamin D, vitamin E, ginger and placebo on the severity of primary dysmenorrhea.

Design
This randomized, double-blind, single- centered clinical trial is a control group. Participants 200 single students aged between 30 and 18 years old living in Qazvin's medical residences who have moderate and severe primary dysmenorrhea.

Settings and conduct
In all groups, medications are taken two days before and three days after menstruation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Single girls aged 18-30 years with regular period of 35-21 days and exclusion criteria: underlying disease; use of contraceptive pills.

Intervention groups
Participants are divided into 4 groups: one group of vitamins E 200 units per day, the second group vitamin D 1000 units once a day, the third group of ginger tablets 500 mg twice a day and the fourth group of placebo tablets twice a day they receive.

Main outcome variables
The severity of pain is measured on the effects of menstrual periods with visual analogue tools before and after the first and second cycles of intervention after intervention.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120104008611N7**
Registration date: **2018-03-09, 1396/12/18**
Registration timing: **retrospective**
Last update: **2018-03-09, 1396/12/18**
Update count: **0**

Registration date
2018-03-09, 1396/12/18

Registrant information

Name
Hamideh Pakniat

Name of organization / entity
Qazvin University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 282242452

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hpakniat@qums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-04-21, 1396/02/01

Expected recruitment end date
2018-01-20, 1396/10/30

Actual recruitment start date
2017-05-22, 1396/03/01

Actual recruitment end date
2017-12-22, 1396/10/01

Trial completion date
empty

Scientific title
Comparison of the effect of vitamin D, vitamin E and ginger on the severity of primary dysmenorrhea among students

Public title
Comparison of the effect of vitamin D, vitamin E and ginger on pain intensity of menstruation among students

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18- 30 year old single girls with a regular menstruation cycles of 21- 35 days The regular period is 35-21 days Duration of 3-7 days Moderate or severe dysmenorrhea

Exclusion criteria:

Underlying disease; and medications Any analgesic Using contraceptive pills Drug and herbal susceptibility

Age

From **18 years** old to **30 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **200**

Actual sample size reached: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are randomly assigned into four groups of intervention and control. Medications are individually encoded in sealed envelopes and delivered to the participants. The participants and the individual who supplies the medication do not know the type of medication in the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

Medications are individually encoded in sealed envelopes and delivered to the participants. The participants and the individual who supplies the medication do not know the type of medication in the envelope But with complete notification and satisfaction, it is included in the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Bahonar Blvd, Qazvin, Iran

City

Qazvin

Province

Qazvin

Postal code

3415613176

Approval date

2016-11-26, 1395/09/06

Ethics committee reference number

IR.QUMS.REC.1395.205

Health conditions studied

1

Description of health condition studied

Primary dysmenorrhea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhea

Primary outcomes

1

Description

Severity of pain

Timepoint

Monthly

Method of measurement

Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Vitamin E 200 units per day

Category

Treatment - Drugs

2

Description

Intervention group: Vitamin D 1000 units once a day

Category

Treatment - Drugs

3

Description

Intervention group: Ginger Pills 500 mg twice a day

Category

Treatment - Drugs

4

Description

Control group: Placebo tablets 2 times a day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Female Dormitories of Ghazvin University of Medical Sciences

Full name of responsible person
Dr Hamideh Pakniat

Street address
Bahonar Blvd, Qazvin, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-Chancellor for Research of Qazvin University of Medical Sciences

Full name of responsible person
Dr. Amir Peymani

Street address
Bahonar Blvd, Qazvin, Iran

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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
Vice-Chancellor for Research of Qazvin 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
Kowsar Hospital

Full name of responsible person
Dr Hamideh Pakniat

Position
Asistant Professor, Department of Obstetrics and Gynecology Qazvin University of Medical Sciences

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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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
Not applicable

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
Not applicable

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Information is the most commonly used questionnaire, which is a statistical analysis

When the data will become available and for how long
Starting 6 months after publication

To whom data/document is available
Only available for people working in academic institutions

Under which criteria data/document could be used
Path analysis

From where data/document is obtainable
Dr Hamideh Pakniat executor of plan

What processes are involved for a request to access data/document
The email will be submitted to the project promoter at the discretion of the information.

Comments