

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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

Email address

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

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

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Bahonar Blvd, Qazvin, Iran

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+98 21 3223 6374

Email

pakniat110@yahoo.com

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 scientific inquiries

Contact

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Qazvin University of Medical Sciences

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Person responsible for updating data

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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

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