

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The comparison of vitamin B1 and placebo effects on the relief of primary dysmenorrhea in university student of Islamic Azad University.

Protocol summary

Summary

This study assesses the impact of vitamin B1 on the intensity of primary dysmenorrhea. Inclusion criteria were included: having primary dysmenorrhea; single; Consent for participates in this study and Exclusion criteria were infected to uterine disease and urinary system; irregular mens and drug using related to dysmenorrhea. This randomized clinical trial is conducted on 124 female students' of Islamic Azad University of Hamedan, Iran, who met the inclusion criteria. The participants are randomly assigned to two groups. The treatment is started by administrating for lotal phase vitamin B1 100mg/day for the experimental group (62 participate in vitamin B1 group) and placebo 1/day for the control group (62 participate in placebo group). Finally, the two groups are compared in terms of the dysmenorrhea severity pain by Visual Analog Scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014071318458N1**

Registration date: **2014-08-29, 1393/06/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-29, 1393/06/07

Registrant information

Name

Mahnaz Azadi Moghtader

Name of organization / entity

Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 818221439

Email address

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Recruitment status

Recruitment complete

Funding source

Islamic Azad university, Hamadan Branch

Expected recruitment start date

2013-07-15, 1392/04/24

Expected recruitment end date

2014-01-14, 1392/10/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of vitamin B1 and placebo effects on the relief of primary dysmenorrhea in university student of Islamic Azad University.

Public title

The comparison of vitamin B1 and placebo effects on the relief of primary dysmenorrhea in university student of Islamic Azad University.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion ceriteria: single women, primary dysmenorrhea; :Consent for participating in this study Exclusion criteria: any uterine disease or urinary system; irregular menstruation; drug using related to dysmenorrhea

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic Azad University, Hamedan Branch

Street address

Islamic Azad University, Hamedan, Iran

City

Hamadan

Postal code

Iran

Approval date

2013-04-21, 1392/02/01

Ethics committee reference number

1367/92

Health conditions studied

1

Description of health condition studied

Primary dysmenorrhea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhoea

Primary outcomes

1

Description

Dysmenorrhea

Timepoint

Study beginning, First Mounth, Second Mouunth

Method of measurement

Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description

Vitamin B1, dose 100 milligram, daily/for 15 day in loteal phase in 2 months

Category

Treatment - Drugs

2

Description

Placebo, dose 100 miligram, daily for 15 day in loteal phase in 2 mouth

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad university of Hamadan

Full name of responsible person

Street address

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University of Hamadan

Full name of responsible person

Dr.Esfandiyari Moghadam

Street address

Islamic Azad University of Hamadan

City

Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University of Hamadan

Proportion provided by this source

100

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
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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