

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of Boron supplementation on the severity of dysmenorrhea in female students residing in dormitories of Shaid Beheshti University of Medical sciences in 2013- 2014

Protocol summary

Summary

General objective: Determine effect of Boron supplementation on the severity of dysmenorrhea in female students residing in dormitories of Shaid Beheshti University of Medical sciences in 2013-14 Design of the study: randomized, triple blind, placebo-controlled. Methods of study: A) The study population: all female students of primary dysmenorrhea residing in dormitories of Shaid Beheshti University of Medical sciences in 2013-14. Study Sample: all female students residing in dormitories of Shaid Beheshti University of Medical sciences in 2013-14 that having condition to enter the study. Inclusion criteria: being single; age between 18 – 25 year old; girls with primary dysmenorrhea that the pain intensity as moderate to severe based Mac Gill ruler; do not suffering from chronic diseases (diabetes, hypertension, cardiac diseases, infectious diseases, liver, kidney); regular menstruation (period between 21 – 35 days); normal BMI (19.8 – 25); have not any symptoms of itching, abnormal discharge during study; not taking any medication, supplements; they should not use any herbal remedies about 3 months ago Intervention; they should not have any deplorable event such as near relatives' death or surgical operation in recent six months. Exclusion criteria: individual's consent to continue participating in the study; pelvic known pathology(myoma, pelvic tumor, endometriosis, PID) during the study; improper use of capsules; any use of herbal drug during the study. Sample size: 108. B) Intervention in study: use Boron supplementation. C) Intervention duration: 2 days before menstruation to 3 first day of bleeding. D) The primary outcome : reduce primery dysmenorrheal after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207153226N5**

Registration date: **2014-05-21, 1393/02/31**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-05-21, 1393/02/31

Registrant information

Name

Mahrokh Dolatian

Name of organization / entity

Shahid Beheshti University of Medical Scenices

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 2512

Email address

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Recruitment status

Recruitment complete

Funding source

Shaid Beheshti University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Boron supplementation on the severity of dysmenorrhea in female students residing in dormitories of Shaid Beheshti University of Medical sciences in 2013-2014		Shaid Beheshti University of Medical sciences- next to Taleghani Hospital- Yemen Street -Chamran Highway -Tehran	
Public title	Effect of Boron supplementation on the severity of dysmenorrhea	City	Tehran
Purpose	Treatment	Postal code	1985717443
Inclusion/Exclusion criteria	Inclusion criteria: being single; age between 18 – 25 year old; girls with primary dysmenorrhea that the pain intensity as moderate to severe based Mac Gill ruler; do not suffering from chronic diseases (diabetes, hypertension, cardiac diseases, infectious diseases, liver, kidney); regular menstruation (period between 21 – 35 days); normal BMI (19.8 – 25); have not any symptoms of itching, abnormal discharge during study; not taking any medication, supplements; they should not use any herbal remedies about 3 months ago Intervention; they should not have any deplorable event such as near relatives' death or surgical operation in recent six months. Exclusion criteria: individual's consent to continue participating in the study; pelvic known pathology(myoma, pelvic tumor, endometriosis, PID) during the study; improper use of capsules; any use of herbal drug during the study.	Approval date	2014-02-09, 1392/11/20
Age	From 18 years old to 25 years old	Ethics committee reference number	400/7554
Gender	Female	Health conditions studied	
Phase	N/A	1	
Groups that have been masked	No information	Description of health condition studied	
Sample size	Target sample size: 108	Primary dysmenorrhoea	
Randomization (investigator's opinion)	Randomized	ICD-10 code	
Randomization description		N94.4	
Blinding (investigator's opinion)	Triple blinded	ICD-10 code description	
Blinding description		Primary dysmenorrhoea	
Placebo	Used	Primary outcomes	
Assignment	Parallel	1	
Other design features		Description	
Secondary Ids	empty	Severity of primary dysmenorrhea	
Ethics committees		Timepoint	
1		Before the intervention, while following intervention during the 3 first day of bleeding in 2cycles.	
Ethics committee		Method of measurement	
Name of ethics committee	Shaid Beheshti University of Medical sciences	Verbal Multidimensional Scoring System Questionnaire, Mac gil ruler.	
Street address		Secondary outcomes	
		1	
		Description	
		Complications	
		Timepoint	
		Finally of bleeding days	
		Method of measurement	
		Questionnaire	
		Intervention groups	
		1	
		Description	
		Intervention group: in people with inclusion criteria To be eaten Boron supplemental, 10 mg, oral daily((2 days before menstruation to 3 first day of bieeding) during 2 cycles. pain intensity with Systemic characteristics associated Will be recorded using Mac gil and Verbal Multidimensional Scoring System .	
		Category	
		Treatment - Drugs	

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Description

Control group: : in people with inclusion criteria To be eaten placebo, contains 300 mg of lactose powder, oral daily (2 days before menstruation to 3 first day of bleeding) during 2 cycles. . pain intensity with Systemic characteristics associated Will be recorded using Mac gil and Verbal Multidimensional Scoring System .

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra'danshgah girl's dormitory, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nikkhah Somayeh// M.Sc Student of Midwifery

Street address

Front Rajai Heart Hospital//Highway intersection niayesh// Valiasr street/tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical sciences

Full name of responsible person

Dr. Masoumeh Simbar

Street address

School of Nursing and Midwifery Shahid Beheshtii/
Front Rajai Heart Hospital / Highway intersection
niayesh/ Valiasr street/Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical sciences

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahrokh Dolatian

Position

MSc in midwifery

Other areas of specialty/work

Street address

Midwifery group /School of Nursing and Midwifery
Shahid Beheshtii/ Front Rajai Heart Hospital / Highway
intersection niayesh/ Valiasr street /Tehran

City

Tehran

Postal code

1985717443

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahrokh Dolatian

Position

MSc in midwifery of Shahid Beheshti University of
Medical sciences

Other areas of specialty/work

Street address

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Somayeh Nikkhah

Position

M.Sc Student of Midwifery

Other areas of specialty/work

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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