Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 in2013-14 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 mensturation 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)
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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

Public title
Effect of Boron supplementation on the severity of dysmenorrhea
Purpose
Treatment
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.
Age
From **18 years** old to **25 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **108**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shaid Beheshti University of Medical sciences
Street address
Shaid Beheshti University of Medical sciences- next to Taleghani Hospital- Yemen Street -Chamran Highway -Tehran
City
Tehran
Postal code
1985717443
Approval date
2014-02-09, 1392/11/20
Ethics committee reference number
400/7554

Health conditions studied

1

Description of health condition studied
Primary dysmenorrhoea
ICD-10 code
N94.4
ICD-10 code description
Primary dysmenorrhoea

Primary outcomes

1

Description
Severity of primary dysmenorrhea
Timepoint
Before the intervention, while following intervention during the 3 first day of bleeding in 2cycles.
Method of measurement
Verbal Multidimentional Scoring System Questionnaire, Mac gil ruler.

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 mensturation to 3 first day of bieeding) during 2 cycles. pain intensity with Systemic characteristics associated Will be recorded using Mac gil and Verbal Multidimentional Scoring System .
Category
Treatment - Drugs

2

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

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MSc in midwifery of Shaid Beheshti University of Medical sciences

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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