

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The comparison of Zinc acetate and placebo (Avicil PH110) effects on primary dysmenorrhea

Protocol summary

Summary

This study is designed as a randomized, double-blind, placebo-controlled clinical trial to investigate effect of Zinc acetate in primary dysmenorrhea in female students of Islamic Azad University Falavarjan Branch dormitory. Then 78 students according to inclusion criteria will be enroll in the study after signing the informed consent sheet and randomly divided into 2 groups. Inclusion criteria were included: having moderate and severe dysmenorrhea and normal cycle and exclusion criteria was improper administration of the medication. The participants in the first group took one capsule of Zinc acetate (30mg) daily for 3 days from beginning of menstruation for two consecutive cycles. Avicil PH110 was used for the placebo group. Intensity of pain was evaluated by Visual Analogue Scale (VAS) and a self-reported checklist was used to collect information of menstruation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062922982N1**

Registration date: **2016-05-17, 1395/02/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-17, 1395/02/28

Registrant information

Name

marzieh javanmardi

Name of organization / entity

islamic azad university falavarjan branch

Country

Iran (Islamic Republic of)

Phone

+98 31 3776 2617

Email address

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Recruitment status

Recruitment complete

Funding source

Islamic Azad University, Falavarjan Branch

Expected recruitment start date

2013-12-18, 1392/09/27

Expected recruitment end date

2015-07-27, 1394/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of Zinc acetate and placebo (Avicil PH110) effects on primary dysmenorrhea

Public title

Effect of Zinc acetate on primary dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Single 18 to 25 years old students, intensity of pain was 4 and more by visual analogue scale (VAS), normal cycle (duration of cycle 21-35, bleeding 3-7 days), no history of abdominal or pelvic surgery or any specific disease such as hepatic, renal and cardiac diseases, diabetes, presence of secondary dysmenorrhea, non consumption of oral contraceptive pills in two months ago, no stressful condition in 3 months ago and during the study like death of family members. Exclusion criteria: Improper administration of the medication, administration of contraceptive pills or

another medication whilst on research, severe stress, not to consent to continue the study.

Age

From **18 years** old to **25 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Double blind means neither the researcher nor the patients know about the type of used drug in the accomplished study. Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar jarib Street, Isfahan

City

Isfahan

Postal code

Approval date

2013-04-22, 1392/02/02

Ethics committee reference number

492002

Health conditions studied

1

Description of health condition studied

dysmenorrhoea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhoea

Primary outcomes

1

Description

dismenorrhea

Timepoint

One month before the intervention and two months after the intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Capsule of Zinc acetate (30mg) daily for 3 days from beginning of menstruation for two consecutive cycles

Category

Treatment - Drugs

2

Description

One capsule of placebo (Avicil PH110) daily for 3 days from beginning of menstruation for two consecutive cycles

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dormitory of Islamic Azad University, Falavarjan Branch

Full name of responsible person

Marzieh Javanmardi

Street address

Islamic Azad University, Falavarjan Branch, Blvd. Daneshgah, Falavarjan

City

Falavarjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Islamic Azad University, Falavarjan Branch

Full name of responsible person

Mrs Barati

Street address

Vice Chancellor for Research, Islamic Azad University,
Falavarjan Branch, Blvd. Daneshgah, Falavarjan

City

Falavarjan

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, Islamic Azad University,
Falavarjan Branch

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

Islamic Azad University, Falavarjan Branch

Full name of responsible person

Marzieh Javanmardi

Position

Master of Science in Midwifery/Academic

Other areas of specialty/work

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Web page address

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