

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 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

javanmardi\_m@iaufala.ac.ir

###### 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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**Phone**

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**Fax**

**Email**

**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*