

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation the effect of oral Aloe vera gel on severity of primary dysmenorrhea in students of Zahedan University of Medical Sciences

#### Protocol summary

##### Summary

Objective: The aim of this study was to evaluate the effect of Aloe vera on pain relief in primary dysmenorrhea. Setting and conduct: The study was conducted at Zahedan University of Medical Sciences Dormitory. Design: The present study was a double-blind, randomized clinical trial. Eighty students with primary dysmenorrhea who signed consent form were participated in this study. Based on random numbers table, the samples were equally divided into two groups and received 1:1 ratio Aloe vera and placebo. All gel bottles were coded at Barij Essence pharmaceutical company which made the products. Because of preventing bias, the researcher and participants did not informed of the kind of oral gel. Inclusion criteria: having score 4 to 10 for dysmenorrhea according to pain scale, no history or no having of uterus and pelvic disease. Exclusion criteria: allergy to drug and take inappropriate dosage and forget the time table. Intervention: The participants took 5cc of oral gel three times a day (two days before until three days after menstrual cycle for two consecutive cycles). If they need to use NSAIDs, allowed them but they must recorded the severity of pain before consumption of the sedative. A self-reported checklist was used to collect information on the number of sedative drugs and condition of menstrual. Also visual analog scale was used to determine severity of pain. Outcome: Severity of pain was assessed at 5 time intervals (first 2 hours from onset of menses, 2 to 12 hours, 12 to 24 hours, second and third day of menstrual cycle).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201206069957N1**

Registration date: **2013-01-29, 1391/11/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-01-29, 1391/11/10

##### Registrant information

###### Name

Somayeh Khazaiyan

###### Name of organization / entity

Zahedan University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 54 1323 1207

###### Email address

khazaiyan@zaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for Research and Technology, Zahedan University of Medical Sciences

##### Expected recruitment start date

2011-12-22, 1390/10/01

##### Expected recruitment end date

2012-06-21, 1391/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation the effect of oral Aloe vera gel on severity of primary dysmenorrhea in students of Zahedan University of Medical Sciences

##### Public title

The effect of Aloe vera gel on menstrual pain

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: being unmarried, having score 4 to 10 for dysmenorrhea according to pain scale, not known chronic diseases, having regular menstrual periods between 21 to 35 days, no history of myoma, pelvic tumor, andometriosis and pelvic inflammatory disease, no taking oral particular drug, no history of allergy to herbal drugs. Exclusion criteria: allergy to Aloe vera during intervention, incorrect taking the drug.

### **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: **80**

### **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**

Research Ethics committee of Zahedan University of Medical Sciences

##### **Street address**

Pardis University of Medical Sciences Campus, Hessabi Sq

##### **City**

Zahedan

##### **Postal code**

9816743463

#### **Approval date**

2011-12-08, 1390/09/17

#### **Ethics committee reference number**

90-1666

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Dysmenorrhea

### **ICD-10 code**

N94.4

### **ICD-10 code description**

Primary dysmenorrhea

## **Primary outcomes**

### **1**

#### **Description**

Severity of primary dysmenorrhea

#### **Timepoint**

3 menstrual cycles, one cycle before the study and 2 cycles during the study with 5 time intervals: first 2 hours from onset of menses, 2 to 12 hours, 12 to 24 hours, second day and third day of menstrual cycle

#### **Method of measurement**

verbal multidimensional scoring system and visual analogue scale

## **Secondary outcomes**

### **1**

#### **Description**

Nausea

#### **Timepoint**

during first 3 days of the menstrual period and at the end of the menstrual period for 2 cycles of intervention

#### **Method of measurement**

Questionnaire (Yes, No)

### **2**

#### **Description**

Vomiting

#### **Timepoint**

during first 3 days of the menstrual period and at the end of the menstrual period for 2 cycles of intervention

#### **Method of measurement**

Questionnaire (Yes, No)

### **3**

#### **Description**

Diarrhea

#### **Timepoint**

during first 3 days of the menstrual period and at the end of the menstrual period for 2 cycles of intervention

#### **Method of measurement**

Questionnaire (Yes, No)

### **4**

#### **Description**

Headache

#### **Timepoint**

during first 3 days of the menstrual period and at the end of the menstrual period for 2 cycles of intervention

#### **Method of measurement**

Questionnaire (Yes, No)

## 5

### Description

Itching

### Timepoint

during first 3 days of the menstrual period and at the end of the menstrual period for 2 cycles of intervention

### Method of measurement

Questionnaire (Yes, No)

## 6

### Description

Hives

### Timepoint

during first 3 days of the menstrual period and at the end of the menstrual period for 2 cycles of intervention

### Method of measurement

Questionnaire (Yes, No)

## Intervention groups

### 1

#### Description

The Aloe vera group took 1 tablespoon Aloe vera gel by oral three times per day from two days before and three days after the beginning of menstrual cycle for two consecutive cycles.

#### Category

Treatment - Drugs

### 2

#### Description

The placebo group took 1 tablespoon placebo gel by oral three times per day from two days before and three days after the beginning of menstrual cycle for two consecutive cycles.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

The dormitory of Zahedan University of Medical Sciences

##### Full name of responsible person

Dr. Mohsen Meskarani

##### Street address

Pardis University of Medical Sciences Campus, Hessabi Sq

##### City

Zahedan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for Research and Technology, Zahedan University of Medical Sciences

##### Full name of responsible person

Dr.Hamid Reza Mahmoodzade Sagheb

##### Street address

Pardis University of Medical Sciences Campus, Hessabi Sq

##### City

Zahedan

#### 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 and Technology, Zahedan 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

Zahedan University of Medical Sciences

##### Full name of responsible person

Mahdiye Donyadari

##### Position

BSc

##### Other areas of specialty/work

##### Street address

School of Nursing and Midwifery, Mashahir Sq

##### City

Zahedan

##### Postal code

9819613396

##### Phone

+98 54 1243 8473

##### Fax

##### Email

m\_20282000@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Zahedan University of Medical Sciences

**Full name of responsible person**

Shahin\_ Dokht Navvabi Rigi

**Position**

Faculty of Midwifery / MSc

**Other areas of specialty/work****Street address**

School of Nursing and Midwifery, Mashahir Sq

**City**

Zahedan

**Postal code****Phone**

+98 54 1341 6706

**Fax**

+98 54 1341 6708

**Email**

shahinnavabi@yahoo.com

**Web page address**

www.zaums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Somaye Khazaiyan

**Position**

Faculty of Midwifery / MSc

**Other areas of specialty/work****Street address**

School of Nursing and Midwifery, Mashahir Sq

**City**

Zahedan

**Postal code****Phone**

00985412419403\_327

**Fax****Email**

m\_khazaiyan@yahoo.com

**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*