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

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Somayeh Khazaiyan
Name of organization / entity
Zahedan University of Medical Science
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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
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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