Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The relationship between date consumption and the severity of dysmenorrhea in women with regular menstrual cycle

Protocol summary

Study aim
The relationship between date consumption and the severity of dysmenorrhea in women with regular menstruation

Design
One-blind phase 2 clinical trial on 26 participants

Settings and conduct
this study was a clinical trial that was performed on 26 female students of the medical school of Dr. Ali Shariati Hospital in Isfahan. the samples were simulated for the severity of dysmenorrhea and then studied randomly. The subjects were examined for the severity of dysmenorrhea, the amount of pain killer consumed and the amount of menstrual bleeding.simultaneously with the onset of menstrual pain (first 3 days of bleeding), 10 dates were distributed by the researcher among the subjects so that they could take the medicine whenever the subjects needed it. pain intensity and systemic symptoms were evaluated and compared using a multidimensional speech system of the study during 2 consecutive cycles with and without consumption of dates, then the results were analyzed using SPSS 17 software with Wilcoxon paired test.Analyzed. The analyzer did not know the characteristics of the subjects and the relevant cycle.

Participants/Inclusion and exclusion criteria
Inclusion criteria included women with reproductive age range of 22-28 years who have painful and regular menstruation And exclusion criteria included Women who refuse to cooperate during the study, women who have irregular menstrual cycles, women who use hormonal medications such as birth control pills during the menstrual cycle, and the presence of severe stress conditions that affect the results of the study, as well as Women who do not follow the relevant diet were identified.

Intervention groups
The target group was studied in three consecutive cycles and the intervention was applied in the second cycle.

Main outcome variables
Pain intensity; Menstrual bleeding rate, analgesic intake

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180708040381N1**
Registration date: **2022-02-05, 1400/11/16**
Registration timing: **retrospective**

Last update: **2022-02-05, 1400/11/16**
Update count: **0**

Registration date
2022-02-05, 1400/11/16

Registrant information

Name
Mehdi Izadi Zaman Abadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3272 4538

Email address
mimi_izadi2@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2011-04-21, 1390/02/01

Expected recruitment end date
2011-08-22, 1390/05/31

Actual recruitment start date
2011-04-21, 1390/02/01

Actual recruitment end date
2011-08-22, 1390/05/31

Trial completion date
2011-09-18, 1390/06/27

Scientific title
The relationship between date consumption and the severity of dysmenorrhea in women with regular menstrual cycle

Public title
The effect of dates on dysmenorrhea

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Women with a reproductive age range of 22-28 years who have painful and regular menstruation

Exclusion criteria:
Women who refuse to cooperate during the study, women who have irregular menstrual cycles, women who use hormonal medications such as birth control pills during the menstrual cycle, and the presence of severe stress conditions that affect the results of the study, as well as Women who do not follow the relevant diet

Age
From **22 years** old to **28 years** old

Gender
Female

Phase
2

Groups that have been masked

- Data analyser

Sample size
Target sample size: **43**
More than 1 sample in each individual
Number of samples in each individual: **3**
Each patient was evaluated in three consecutive menstrual cycles.
Actual sample size reached: **26**
More than 1 sample in each individual
Actual sample size in each individual: **3**
Each patient was evaluated in three consecutive menstrual cycles.

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
The analyzer did not know who the data belonged to and which menstrual cycle it belonged to.

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Islamic Azad University - Khomeini Shahr Branch

Street address
Isfahan - Khomeini Shahr - Manzaria - End of Daneshjoo Boulevard - Islamic Azad University Khomeini Shahr Branch

City
Khomeini Shahr

Province
Isfehan

Postal code
۸۴۱۸۱۴۸۴۹۹

Approval date
2022-01-23, 1400/11/03

Ethics committee reference number
طبق نامه شماره 3152/1-13-04 که به پیوست ارسال می گردد.

Health conditions studied

1

Description of health condition studied
primary dysmenorrhea

ICD-10 code
N94.4

ICD-10 code description
Primary dysmenorrhea

Primary outcomes

1

Description
Intensity of pain

Timepoint
Monthly for 3 consecutive months

Method of measurement
VAS score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 10 of Bam Mazafati dates in the second cycle of menstruation

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr. Shariati Hospital, Isfahan
Full name of responsible person
Dr. Abbas Ali Nasr Isfahani
Street address
Sichan, chahar bagh bala, Taj al-Din alley
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University - Najafabad Branch
Full name of responsible person
Dr. Farid Naimi
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Islamic Azad University - Najafabad Branch

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Mehdi Izadi Zaman Abadi
Position
Anesthesiologist
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All content and study data will be shared after publication.
When the data will become available and for how long
Access will start from the time the article is published.
To whom data/document is available
All authors and managing director of the publication
Under which criteria data/document could be used
To use the contents of this study in dissertations or articles,Students and researchers have access to the documents of this study.
From where data/document is obtainable
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What processes are involved for a request to access data/document
Email or request will be read,and after consulting with other authors, the request will be reviewed and answered.
Comments