

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of drinking water on the severity of primary dysmenorrhea, amount and variety of drugs consumed and quality of life in female students

Protocol summary

Study aim

Determining the effect of modifying the pattern of drinking water on the severity of dysmenorrhea, the amount and variety of drugs consumed.

Design

The girls who think that they consume less than 8 glasses of water per day and have early dysmenorrhea, are invited to enter the study. First, the severity of dysmenorrhea in girls will be examined by using a visual scale. Individuals who choose at least 3 out of 10, will be selected. Then they will record daily water intake for at least 5 days. If they take less than 8 glasses of water each day, they will be included in the study.

Settings and conduct

This research will be carried out at the Islamic Azad University of Isfahan (Khorasgan). Girls who have primary dysmenorrhea and drink less than 8 glasses of water per day will be included in the study.

Participants/Inclusion and exclusion criteria

History of primary dysmenorrhea drinking less than 8 glass per day (each glass contains 250 cc)

Intervention groups

Samples will drink 8 to 10 glass of water every day.

Main outcome variables

Reducing the consumption of pain relievers for dysmenorrhea, promote girls' health, improve their quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180708040377N1**

Registration date: **2020-04-16, 1399/01/28**

Registration timing: **retrospective**

Last update: **2020-04-16, 1399/01/28**

Update count: **0**

Registration date

2020-04-16, 1399/01/28

Registrant information

Name

Behnaz Torkan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3535 4058

Email address

torkan@khuisf.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-26, 1396/02/06

Expected recruitment end date

2018-04-26, 1397/02/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of drinking water on the severity of primary dysmenorrhea, amount and variety of drugs consumed and quality of life in female students

Public title

The effect of drinking water on severity of dysmenorrhea

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Students who have primary dysmenorrhea Students who drink less than 8 glass of water(totally 1600 milliliter)

Exclusion criteria:

History of medical disease like renal, heart, respiratory disease or diabet; Uterine disorders like myoma and endometriosis; Suffering from secondary dysmenorrhea.

Age

From **18 years** old to **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Arghavanieh Bulvard, Postcode: 33998-81551

City

Isfahan

Province

Isfahan

Postal code

39998-81551

Approval date

2016-07-05, 1395/04/15

Ethics committee reference number

IR.MUI.REC.1395.4.076

Health conditions studied

1

Description of health condition studied

Primary dysmenorrhea

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of Primary Dysmenorrhea

Timepoint

One month and two months after modifying the pattern of water drinking

Method of measurement

Questionnaire and Visual Analogue Scale

Secondary outcomes

1

Description

Severity of primary dysmenorrhea, menstrual characteristics and the amount of analgesics used

Timepoint

One month and two months after modifying the pattern of water drinking

Method of measurement

Questionnaire and Visual Analogue Scale for dysmenorrhea

Intervention groups

1

Description

Intervention group: Students who have primary dysmenorrhea and drink less than 8 glasses of water per day will receive water drinking instructions. They will repeat this procedure for two continuous menstrual cycles. During both menstrual bleeding, the severity of dysmenorrhea and intake of analgesics will be investigated.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University, Isfahan(Khorasgan) Branch, Post code:39998-81551

Full name of responsible person

Behnaz Torkan

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torkan@khuisf.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Majid Toghyani

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Email

m.toghiani@khuisf.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Behnaz Torkan

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to

make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Participant's individual data after unidentifiable individuals can be shared

When the data will become available and for how long

Access will start 6 months after the results are printed.

To whom data/document is available

Data will only be available to researchers working at academic and scientific institutions.

Under which criteria data/document could be used

It is allowed to conduct analyzes that lead to the obtaining of relevant research data

From where data/document is obtainable

Please refer to "Behnaz Torkan" at torkan@khuif.ac.ir for documentation.

What processes are involved for a request to access data/document

It will take a maximum of one month to send the documentation at the request of the applicant.

Comments