

# 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

##### Street address

Arghavanieh Bulvard, Post code: 39998-81551

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+98 31 3535 4058

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**Email**

torkan@khuisf.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Majid Toghyani

**Street address**

Arghavanieh Bulvard, Post code: 39998-81551

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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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Islamic Azad University

**Full name of responsible person**

Behnaz Tokran

**Position**

Faculty Member

**Latest degree**

Master

**Other areas of specialty/work**

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## Person responsible for updating data

#### Contact

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Islamic Azad University

**Full name of responsible person**

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Faculty member

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**Email**

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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**