

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of licorice syrup on primary dysmenorrhea compared with Ibuprofen

#### Protocol summary

##### Summary

The purpose of this study is to compare the effect of licorice syrup with ibuprofen on moderate to severe primary dysmenorrhea. Here, primary dysmenorrhea will be diagnosed by patients' medical history and moderate to severe dysmenorrhea will be based on verbal multidimensional scoring system. Our case study will be sixty patients aged between 18-25 years old with no any other known disease and will have entered the study after obtaining consent. Patients will be sampled from the students living in Tehran dormitories or patients referring to traditional medicine clinic of Tehran Imam Khomeini hospital. It is worth mention that, demographic information and history of dysmenorrhea including severity and duration of pain in the last menstrual cycle will be registered before enrolling the study. One of the two groups, enrolled randomly by a computer coding, will have received Ibuprofen 400 mg every 8 hours and placebo syrup and the other will have received Licorice syrup 5 cc 2 times a day and placebo tablets. The patients will have taken the drug from the first day of menstruation to 5th and for two consequent cycles. We will evaluate the primary pain intensity and its changes by visual analogue scale and the duration of pain by hour during the study. Here participants, observers and analysts do not have any information about the patients within the groups. It should be noted that, although the patients are permitted to use Acetaminophen if needed, reporting the dose for ultimate comparison is necessary.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015081323610N1**

Registration date: **2016-02-17, 1394/11/28**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-02-17, 1394/11/28

##### Registrant information

###### Name

Zahra Jafari

###### Name of organization / entity

Faculty of Traditional Medicine, Shahid Sadougei University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 353223891

###### Email address

z-jafari@razi.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for research, Shahid sadoughi University of Medical Sciences and Health Services, Yazd

##### Expected recruitment start date

2015-12-22, 1394/10/01

##### Expected recruitment end date

2016-06-20, 1395/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of licorice syrup on primary dysmenorrhea compared with Ibuprofen

##### Public title

The effect of licorice syrup on dysmenorrhea

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion Criteria: Aged between 18-25 years; Moderate and severe dysmenorrhea (grade 2, 3) based on Verbal Multidimensional Scoring System; Regular menstrual cycles (every 21-35 days and bleeding 3 to 10 days for at least three recent cycles). Exclusion criteria: Pelvic pathology (including Endometriosis, Adenomyosis, Fibroids, Ovarian Cysts, Pelvic Inflammatory Disease, etc); Known diseases (including Chronic Hepatitis, Cholestatic Liver Disease, Cirrhosis, Severe Renal Insufficiency, Diabetes Mellitus, Arrhythmias, Hypertension, Hypertonia and Hypokalemia); Existence of stressors (such as loss of a close relative and Intense familial debate) during recent 6 months; History of allergy to licorice; Concurrent use of other products containing licorice; Taking another painkiller that is not defined in the study; Concomitant use of OCP; Drug intolerance; Lack of desire to continue the treatment for any reason; Another disease that will have required medical treatment during the study.

### **Age**

From **18 years** old to **25 years** old

### **Gender**

Female

### **Phase**

3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **60**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Triple blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

The mentioned scientific name has been registered unchanged as approved by the University Research Council.

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Shahid Sadoughi University of Medical Sciences

##### **Street address**

Central department of Shahid Sadoughi University of Medical Sciences, Shahid Bahonar Sq.

##### **City**

Yazd

##### **Postal code**

8916978477

##### **Approval date**

2015-11-30, 1394/09/09

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

IR.SSU.REC.1394.121

## **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**

Pain intensity

#### **Timepoint**

Before intervention- Every day during intervention

#### **Method of measurement**

Visual Analogue Scale(VAS)

### **2**

#### **Description**

Pain duration

#### **Timepoint**

Before intervention- Every day during intervention

#### **Method of measurement**

hour

## **Secondary outcomes**

### **1**

#### **Description**

adverse effect of licorice syrup

#### **Timepoint**

At the end of each cycle of intervention

#### **Method of measurement**

Questionnaire

### **2**

#### **Description**

adverse effect of Ibuprofen such as Nausea, dyspepsia, vomiting, ulcers and gastrointestinal bleeding

#### **Timepoint**

At the end of each cycle of intervention

#### **Method of measurement**

Questionnaire

## Intervention groups

### 1

#### Description

Intervention Group: licorice syrup at a dose of 5 mL twice daily and placebo every 8 hours during the first five days of each cycle and for two consecutive cycles

#### Category

Treatment - Drugs

### 2

#### Description

Control Group: Ibuprofen 400 mg every 8 hours and 5 ml of placebo syrup twice a day, during the first five days of each cycle and for two consecutive cycles

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Traditional medicine clinic of Imam Khomeini hospital

##### Full name of responsible person

zahra jafari

##### Street address

Imam Khomeini Hospital, Keshavarz Blvd.

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for research, Shahid Sadougehi University of Medical Sciences

##### Full name of responsible person

Dr. Fatemeh Ezoddini

##### Street address

Central department of Shahid Sadougehi Medical University, Shahid Bahonar Sq.

##### City

Yazd

#### 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, Shahid Sadougehi 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

Faculty of Traditional Medicine, Shahid Sadougehi University of Medical Sciences, Ardakan, Yazd

##### Full name of responsible person

zahra jafari

##### Position

Phd student of Iranian Traditional Medicine

##### Other areas of specialty/work

##### Street address

Imam Khomeini Ave.

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z-jafari@razi.tums.ac.ir

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Faculty of Traditional Medicine, Shahid Sadougehi University of Medical Sciences, Ardakan, Yazd

##### Full name of responsible person

Dr. Majid Emtiazy

##### Position

Assistant Professor

##### Other areas of specialty/work

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## Person responsible for updating data

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##### Full name of responsible person

Zahra Jafari

**Position**

PhD student of Traditional Medicine

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

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**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*