Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Sadoughei University of Medical Sciences

Country

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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 Sadoughei University of Medical Sciences
Full name of responsible person
Dr. Fatemeh Ezoddini
Street address
Central department of Shahid Sadoughei 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 Sadoughei 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 Sadoughei University of Medical Sciences, Ardakan, Yazd
Full name of responsible person
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Person responsible for updating data

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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