

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The Effect of Eryngium Syrup on Primery Dysmenorrhea and comparison with Ibuprofen Syrup; Clinical Control Trial

Protocol summary

2015-11-18, 1394/08/27

Summary

The purpose of the study is to compare the effect of "Gharasaneh" Syrup with Ibuprofen Syrup and placebo on primary dysmenorrhea. One hundred fifty 30-18years old students, who are resident in dormitory with considering inclusion and exclusion criteria, will enter the study. Enrolling in 3 groups of "Gharasaneh" Syrup, Ibuprofen Syrup and placebo cases will be done with simple sampling and random allocation. Design and performance of the study are double blind. The cases are obtained written informed consent and will explain them that enrolling in the groups is randomly. The forms of Demographic information will be completed and also history of dysmenorrhea including the severity of pain (based on Visual Analogue Scale) and the time duration of pain in the last menstrual cycle before enrolling in to the study. The dosages in three groups are 10 ml TDS. They will be prescribed 3 days before probable bleeding time up to the 3rd day of bleeding. The treatment is continued for 2 consecutive cycles. Pain severity is measured at the end of first and second months of medication and two consecutive menstrual cycles after the study and will compared with the baseline data. The study design is founding on Acetaminophen consumption as Rescue Dose and reporting the dosage of it in Placebo and "Gharasaneh" group.

Registrant information

Name

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Name of organization / entity

Babol University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences School of Traditional Medicine

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-05-14, 1395/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Eryngium Syrup on Primery Dysmenorrhea and comparison with Ibuprofen Syrup; Clinical Control Trial

Public title

The effect of "Gharasaneh" Syrup on Dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18 to 30; Primary

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015082823789N1**

Registration date: **2015-11-18, 1394/08/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

dysmenorrhea (pain is started 1 to 2 years after menarche during the menstruation and does not appear any other time) exclusion criteria: Heavy exercise; Taking other drugs during the study; Concomitant use of hormonal contraceptive methods; History of allergy to herbal medicine; Severe stress (Such as the loss of a close relative, Intense familial debate, some other stress factor during recent 6 months)

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Babol University of Medical Science-Deputy Ministry for Research and Technology

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Approval date

2015-07-28, 1394/05/06

Ethics committee reference number

Mubabol.rec.1394.113

Health conditions studied**1****Description of health condition studied**

dysmenorrhoea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhoea

Primary outcomes**1****Description**

severity of pain

Timepoint

Before intervention, 2 month after beginning intervention

Method of measurement

Visual Analogue scale

2**Description**

severity of pain

Timepoint

first menstrual cycle after study

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups**1****Description**

"Gharasaneh" syrup; it will be prescribed 3 days before probable bleeding time up to the 3rd day of bleeding. The dosage is 10 ml TDS. The treatment is continued for 2 consecutive cycles.

Category

Treatment - Drugs

2**Description**

Ibuprofen syrup (200mg/5cc); it will be prescribed 3 days before probable bleeding time up to the 3rd day of bleeding. The dosage is 10 ml TDS. The treatment is continued for 2 consecutive cycles.

Category

Treatment - Drugs

3**Description**

Placebo syrup; it will be prescribed 3 days before probable bleeding time up to the 3rd day of bleeding. The dosage is 10 ml TDS. The treatment is continued for 2 consecutive cycles.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Female Dormitory of Tehran University

Full name of responsible person

Elham Behmanesh

Street address

End of Kargar St, Tehran University dormatory

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Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Ali Bijani

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Ganjafrooz Street, Babol University of Medical Sciences

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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

Babol 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

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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