

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of Plantago Syrup and Mefenamic Acid Capsule Hypermenorrhea

Protocol summary

Summary

The aim of this study is to compare the effect of Plantago syrup with mefenamic acid capsule on hypermenorrhagia. In this study, women between the ages of 36 and 45 have a normal gynecology examination and healthy pap smear and have menstrual bleeding of more than 7 days or 80 cc per month. People who have potential side effects or require surgical intervention are excluded. The sample size is 68, Based on random assignment divided into two groups of 34 people. The probable time to reach this sample size is one year. In a group of Plantago syrup, in the first 5 days of the menstrual cycle, 5 cc is given every 8 hours with the placebo capsule every 8 hours and in the other group, Mefenamic acid capsule will be given every 8 hours in the first 5 days of the menstrual period, with a placebo syrup of 5 cc every 8 hours. The duration and severity of menstruation will be measured at baseline and after three periods of menstruation. This is a three-blind study. The therapist, patient and analyzer are not aware of interventional groups and placebo.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061634576N1**

Registration date: **2017-08-19, 1396/05/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-08-19, 1396/05/28

Registrant information

Name

Mozhdeh Khodabakhsh

Name of organization / entity

Deputy of Research and Technology of Mashhad
University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology of Mashhad
University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Plantago Syrup and
Mefenamic Acid Capsule Hypermenorrhea

Public title

Comparison of the effect of Plantago Syrup and
Mefenamic Acid Capsule Hypermenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Criteria for entering the study of outpatients between the ages of 36-45 years with a complaint of hypermenorrhoea that have negative pregnancy tests and not being breast-fed; The patient has no desire for hormonal treatment (ocp); Genic examination is normal; Pap smear

sample of the patient is healthy;At the same time as hormonal treatments,Not use to other Herbal remedies and herbs; A month before entering in to the study,Doesn't use any drug to heal much hemorrhage;Use non-hormonal prevention;Hb is between 11 and 14;A patient with diabetes,Does not have uncontrolled blood pressure, congestive heart disease, and blood dislocations;The patient has no history of chronic diseases such as lupus and thyroid problems;The patient does not have a history of uterine malformations, ovaries, or other malignancies;Patient does not have hyperichotheneemia ;Does not have IUD;The BMI is between 18/5 and 30;No fibroma.Exit criteria for patients who get pregnant during the study;Patients who use hormonal drugs during the study;Patients with possible side effects;Patients who require other interventions and have surgery;Patients who decide to leave the study with a personal request;The bleeding during the study is so severe that it requires emergency procedures.

Age

From **36 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

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

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Mashhad University of Medical Sciences

Street address

University of Science and Technology, Faculty of Science and Technology, Mashhad University of Medical Sciences

City

Mashhad

Postal code**Approval date**

2017-08-03, 1396/05/12

Ethics committee reference number

IR.MUMS.REC.1396.42

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

Hymenorrhea

ICD-10 code

N92.0

ICD-10 code description

Excessive and frequent menstruation with regular cycle

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

Severity and duration of menstrual bleeding

Timepoint

Beginning of the study and after three periods

Method of measurement

PBAC chart

Secondary outcomes

empty

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

There are two intervention groups in the study group. The serum of Barragon syrup is given at 5 cc every 8 hours in the first 5 days of menstruation. In the other group, the muscle capsule is given every 8 hours once in the first 5 days of menstruation.

Category

Treatment - Drugs

2**Description**

Placebo group Placebo syrup 5 cc every 8 hours with Mefenamic acid capsule is given one every 8 hours.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Clinic of Ghaem Hospital

Full name of responsible person

Mozhdeh Khodabakhsh

Street address

Taghi Abad square of Ghaem Hospital

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and Technology of Mashhad
University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Full Description University of Science and Technology,
Faculty of Science and Technology, Mashhad
University of Medical Sciences

City

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Deputy of Research and Technology of Mashhad
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**

School of Traditional Medicine and Mashhad
Supplement

Full name of responsible person

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Position

Traditional Iranian Traditional Medicine

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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