

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3845 3876

##### Email address

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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**

Mozhdeh Khodabakhsh

**Position**

Traditional Iranian Traditional Medicine

**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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**Position**

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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*