

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation of the effect of acupuncture on regulating the menstrual cycle in the patients with abnormal uterine bleeding

#### Protocol summary

##### Study aim

Determining the effect of acupuncture in regulating the menstrual cycle in patients with abnormal uterine bleeding

##### Design

Randomized Clinical Trial Intervention and control groups, Simple randomization Blinding of the analyst The sample size in each group : 34

##### Settings and conduct

Women of reproductive age referring to women's clinics of Mashhad University of Medical Sciences with complaints of abnormal uterine bleeding are examined in two intervention and control groups. First, their demographic information including age, marriage date, number of pregnancies, number of live children, number of abortions, number of births and their methods, prevention method, complete history of menses ,pads for use in every cycle, vaginal bleeding as clots, need to change pads at night, symptoms of Anemia, drugs used, the results of laboratory tests and ultrasound, pap smear are recorded and requested if necessary. A detailed gynecological examination is performed by the researcher for all patients. Both groups are treated with routine drugs such as non-steroidal anti-inflammatory drugs, tranexamic acid, progestins or combined estrogen-progesterone pills for 3 months. In the intervention group, adjuvant treatment with acupuncture also is started at the same time. For patients in the intervention group, 12 sessions of acupuncture treatment are performed weekly.

##### Participants/Inclusion and exclusion criteria

Patients with abnormal uterine bleeding without structural disorders are included in the study.

##### Intervention groups

Patients are treated with estrogen-progesterone, progestin-only, non-steroidal anti-inflammatory drugs, tranexamic acid, and 12 weekly sessions of acupuncture.

##### Main outcome variables

Length of menstrual cycle, duration of menstrual

bleeding, intensity of monthly bleeding, frequency of menstrual habits

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190202042596N2**

Registration date: **2022-11-09, 1401/08/18**

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

Last update: **2022-11-09, 1401/08/18**

Update count: **0**

##### Registration date

2022-11-09, 1401/08/18

##### Registrant information

##### Name

Mahnaz Boroumand Rezazadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3602 3459

##### Email address

boroumandrm@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-10-22, 1401/07/30

##### Expected recruitment end date

2023-10-22, 1402/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effect of acupuncture on regulating the menstrual cycle in the patients with abnormal uterine bleeding

**Public title**

Acupuncture for treatment of abnormal uterine bleeding

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Irregular menstrual cycle in the form of: 1- Polymenorrhea (menstrual cycle time less than 21 r) 2- Oligomenorrhea (menstrual cycle duration more than 35 days) 3-Bleeding between cycles 4-Spotting before or after menopause 5-hypermenorrhea (uterine bleeding more than 80 cc In each cycle, blood clot excretion more than 2 hours, the need to replace the night pad, severe uterine bleeding leading to anemia) 6-Absence of structural disorders justifying bleeding such as Fibroids, polyps, hyperplasia, cancer, adenomyosis, etc. 7-Consent to participate in the study and use of acupuncture 9-No Acupuncture Contraindications - Acupuncture Contraindications: Pregnancy, skin problems such as infection or inflammation at the site of acupuncture

**Exclusion criteria:**

1-Trauma 2-Drugs 3-Postpartum 4-Structural disorders such as fibroids, polyps, hyperplasia, cancer, adenomyosis, etc. 5-Failure to follow the course of treatment, 6-Postmenopausal bleeding 7-Vaginal bleeding due to pregnancy complications

**Age**

To 50 years old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 76

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients are randomly divided into intervention and control groups using the random block method using the website sealedenvelop.com. Allocation concealment will be done using opaque, sealed and numbered envelopes

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Mashhad Medical School

**Street address**

Sanabad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138943662

**Approval date**

2022-09-18, 1401/06/27

**Ethics committee reference number**

IR.MUMS.MEDICAL.REC.1401.307

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

Abnormal uterine bleeding

**ICD-10 code**

N93.9

**ICD-10 code description**

Abnormal uterine and vaginal bleeding, unspecified

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

Length of menstrual cycle

**Timepoint**

The period of six months- The duration of the monthly menstrual cycle is checked before the intervention and immediately after the completion of the three-month course of acupuncture and drug treatment and three months after the end of the intervention.

**Method of measurement**

Reassessment of signs & symptoms

**2****Description**

Duration of menstrual bleeding

**Timepoint**

The period of six months- The duration of the monthly menstrual bleeding is checked before the intervention and immediately after the completion of the three-month course of acupuncture and drug treatment and three months after the end of the intervention.

**Method of measurement**

Reassessment of signs & symptoms

### 3

#### **Description**

Intensity of monthly bleeding

#### **Timepoint**

The period of six months- The intensity of monthly bleeding is checked before the intervention and immediately after the completion of the three-month course of acupuncture and drug treatment and three months after the end of the intervention.

#### **Method of measurement**

Reassessment of signs & symptoms

### 4

#### **Description**

Frequency of menstrual habits

#### **Timepoint**

The period of six months- The frequency of menstrual habits is checked before the intervention and immediately after the completion of the three-month course of acupuncture and drug treatment and three months after the end of the intervention.

#### **Method of measurement**

Reassessment of signs & symptoms

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention Group: 12 weekly acupuncture treatment sessions besides routine drugs for example progestogenic pills such as tab medroxyprogesterone for 10 days, 10 mg daily from the 14th day of the cycle, cyclic tab combined estrogen-progesterone pills, non-steroidal anti-obesity drugs such as cap mefenamic acid 500 mg q 8 h and cap tranexamic acid 500 mg q 8 h

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: Routine Drugs for example progestogenic pills such as medroxyprogesterone, combined estrogen-progesterone pills, non-steroidal anti-obesity drugs and tranexamic acid

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Gynecology clinics of teaching hospitals of Mashhad University of Medical Sciences

#### **Full name of responsible person**

Dr. Majid Ghayor Mobarhan

#### **Street address**

University Street

#### **City**

Mashhad

#### **Province**

Razavi Khorasan

#### **Postal code**

9138813944

#### **Phone**

+98 51 3841 1538

#### **Email**

boroumaandrm@mums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Mashhad University of Medical Sciences

##### **Full name of responsible person**

Dr. Majid Ghayour Mobarhan

##### **Street address**

University Street

##### **City**

Mashhad

##### **Province**

Razavi Khorasan

##### **Postal code**

9138813944

##### **Phone**

+98 51 3841 1538

##### **Email**

GhayourM@mums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Mashhad University of Medical Sciences

#### **Proportion provided by this source**

100

#### **Public or private sector**

Public

#### **Domestic or foreign origin**

Domestic

#### **Category of foreign source of funding**

empty

#### **Country of origin**

#### **Type of organization providing the funding**

Academic

## **Person responsible for general inquiries**

#### **Contact**

##### **Name of organization / entity**

Mashhad University of Medical Sciences

##### **Full name of responsible person**

Mahnaz Boroumand Rezazadeh

**Position**

Academic Staff

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Sanabad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138943662

**Phone**

+98 51 3842 1052

**Email**

boroumandrm@mums.ac.ir

**Position**

medical faculty

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Sanabad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138943662

**Phone**

+98 51 3842 1052

**Email**

boroumandrm@mums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mahnaz Boroumand Rezazadeh

**Position**

Medical Faculty

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Sanabad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138943662

**Phone**

+98 51 3842 1052

**Email**

boroumandrm@mums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mahnaz Boroumand Rezazadeh

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Information on the main outcomes is shared

**When the data will become available and for how long**

The access period begins three months after the publication of the results

**To whom data/document is available**

Academic researchers

**Under which criteria data/document could be used**

Using data to check the quality of analysis

**From where data/document is obtainable**

Mahnaz Boroumand Rezazadeh Department of Obstetrics and Gynecology, Mashhad University of Medical Sciences

**What processes are involved for a request to access data/document**

one month after request

**Comments**