Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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+98 51 3602 3459

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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
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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
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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
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Person responsible for scientific inquiries

Contact
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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
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Person responsible for updating data

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
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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 Gyneccology, Mashhad University of Medical Sciences
What processes are involved for a request to access data/document
one month after request
Comments