Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of Commiphora mukul capsule and mefenamic acid on menorrhagia: A-triple-blind randomized clinical trial

Protocol summary

Study aim
Comparison of the effect of commiphora mukul capsule with mefenamic acid on abnormal menstrual bleeding (menorrhagia)

Design
triple-blind clinical trial, randomized with R software, on 60 patients (two groups of 30)

Settings and conduct
Patients referred to the gynecological clinic of Afzalipour Hospital and health centers in Kerman, Iran, after confirmation of idiopathic menorrhagia by a gynecologist and performing the necessary tests, enter the study with informed consent. The capsules are in the same package and the doctor and the patient are not aware of its contents.

Participants/Inclusion and exclusion criteria
Login Criteria: 18 to 55 years old idiopathic menorrhagia Normal coagulation tests Normal thyroid hormones Normal Prolactin test Normal ultrasound (absence of fibroma larger than 5 mm and other anatomical problems) Negative pregnancy test Signature informed consent Exit Criteria: Sensitivity to study drugs Failure to follow the treatment method of the study Reluctance to continue participating in the study

Intervention groups
Women aged 18 to 55 years with idiopathic menorrhagia living in Kerman, Iran

Main outcome variables
-Volume and number of bleeding days in women with idiopathic menorrhagia -Hemoglobin levels in patients with menorrhagia -Quality of life of patients with menorrhagia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211125053177N1**
Registration date: **2022-05-05, 1401/02/15**
Registration timing: **prospective**

Last update: **2022-05-05, 1401/02/15**
Update count: **0**

Registration date
2022-05-05, 1401/02/15

Registrant information

Name
Asma Ahmadzadeh Heshmati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3253 2275

Email address
a.ahmadzade1388@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-11, 1401/04/20

Expected recruitment end date
2023-03-20, 1401/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of Commiphora mukul capsule and mefenamic acid on menorrhagia: A-triple-blind randomized clinical trial

Public title
Comparison of the effect of Commiphora mukul and

mefenamic acid on abnormal mensural bleeding

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Menorrhagia no history of known systemic or inflammatory pelvic diseases not pregnant Do not take certain medications not having a Pap smear and abnormal ultrasound not having a history of allergies to herbs

Exclusion criteria:

Age

From **15 years** old to **55 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Assignment of patients to the two groups is done using the randomized block method in 4 blocks. Random random block table for two groups using R software is prepared as follows: B A A A A B A A B B A A B B B B A A B B A A A B B A B B A B B A A B B A B A B A A B A A B B A A A B B B B A B A A B A

Blinding (investigator's opinion)

Triple blinded

Blinding description

The capsule containing the Commiphora mukul extract will be very similar in appearance to the mefenamic acid capsule, the packaging of the drugs is the same and coded, and the way both drugs are used is the same. The patient, physician, and statistician do not know which drug each code belongs to

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences campus, the beginning of Haft Bagh Alavi axis

City

Kerman

Province

Kerman

Postal code

1355576169

Approval date

2022-03-08, 1400/12/17

Ethics committee reference number

IR.KMU.REC.1400.666

Health conditions studied

1

Description of health condition studied

menorrhagia

ICD-10 code

N92.0

ICD-10 code description

Excessive and frequent menstruation with regular cycle

Primary outcomes

1

Description

Menstrual bleeding volume and number of bleeding days based on Pictorial blood loss assessment chart (PBLAC)Hemoglobin level in CBC (Complete Blood Count) test

Timepoint

The seventh day of each cycle and if bleeding continues, the evaluation is done every week for up to three cycles

Method of measurement

Pictorial blood loss assessment chart (PBLAC), CBC (Complete Blood Count) laboratory test

Secondary outcomes

1

Description

Quality of Life

Timepoint

Beginning and end of the study (after the end of the third menstrual cycle)

Method of measurement

MQ Questionnaire

Intervention groups

1

Description

The first intervention group receives a 250 g capsule containing commiphora mukul powder every 8 hours

every month from the first to the fifth day of menstrual bleeding for 3 consecutive months.

Category

Treatment - Drugs

2

Description

The second intervention group receives a 250 g capsule of mefenamic acid every 8 hours every month from the first to the fifth day of menstrual bleeding for 3 consecutive months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour hospital clinic

Full name of responsible person

Asma Ahmadzadeh Heshmati

Street address

Unit One, Second Apartment on the left (Golshan Apartment), NO.8, Neshat Park

City

Kerman

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Postal code

7613648443

Phone

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Email

a.ahmadzade1388@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Reza Malekpour Afshar

Street address

Deputy of Research and Technology, Somayeh Crossroads (Tahmasb Abad) at the beginning of Ibn Sina Street

City

Kerman

Province

Kerman

Postal code

7619813159

Phone

+98 34 3226 3719

Fax

+98 34 3226 3857

Email

VCR@KMU.AC.IR

Web page address

https://vresearch.kmu.ac.ir/fa

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Asma Ahmadzadeh Heshmati

Position

PhD student in Iranian medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Unit One, Second Apartment on the left (Golshan Apartment), NO.8, Neshat Park

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Study data is published with confidentiality.

When the data will become available and for how long

After publishing the article

To whom data/document is available

The data is accessible to all researchers.

Under which criteria data/document could be used

The analyzed data can be used only by mentioning the source.

From where data/document is obtainable

scientific respondent of the study

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

The study data can be received through the e-mail of the scientific respondent of the study

Comments