Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the therapeutic effects of HABES herbal syrup on abnormal uterine bleeding in women with hypermenorrhea

Protocol summary

Study aim
To evaluate and compare the therapeutic effects of HABES herbal syrup and Golnar capsule on abnormal uterine bleeding in women with hypermenorrhea, in comparison with an active control (tranexamic acid).

Design
This study is a randomized, controlled, single-center clinical trial with three parallel arms, in which participants are allocated using permuted block randomization and the study is conducted as single-blind.

Settings and conduct
This study is conducted at the Royā Infertility Treatment Center (ACECR), Qom, Iran. Eligible participants are enrolled after written informed consent and randomly assigned to study groups, with all interventions and assessments performed according to the study protocol at the same center.

Participants/Inclusion and exclusion criteria
Women aged 20–55 years diagnosed with menorrhagia (hypermenorrhea) due to uterine fibroid or endometrial polyp who are candidates for hysteroscopy and have menstrual bleeding lasting more than seven days with abnormal uterine bleeding at irregular intervals will be eligible for inclusion in this study. Women with gastrointestinal disorders or any chronic disease requiring long-term treatment, those who are pregnant or breastfeeding, and individuals with immune system–related diseases will be excluded from the study.

Intervention groups
Participants are randomly assigned to three parallel groups receiving HABES herbal syrup, Golnar capsule, or active control (tranexamic acid), according to the study protocol.

Main outcome variables
The primary outcomes of this study include reduction in menstrual bleeding severity assessed by the Pictorial Blood Loss Assessment Chart (PBAC), reduction in the duration of menstrual bleeding, and improvement in quality of life following the interventions.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251221068398N1**
Registration date: **2026-02-11, 1404/11/22**
Registration timing: **registered_while_recruiting**

Last update: **2026-02-11, 1404/11/22**
Update count: **0**

Registration date
2026-02-11, 1404/11/22

Registrant information

Name
Faezeh Davoodi Asl
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 25 3270 0155
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faezehdavoodi1363@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-02-09, 1404/11/20

Expected recruitment end date
2028-02-09, 1406/11/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigating the therapeutic effects of HABES herbal syrup on abnormal uterine bleeding in women with hypermenorrhea

Public title
Therapeutic effects of herbal medicines on abnormal uterine bleeding

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women diagnosed with menorrhagia (hypermenorrhea) due to uterine fibroid or endometrial polyp who are candidates for hysteroscopy Age between 20 and 55 years Menstrual bleeding lasting more than 7 days with abnormal uterine bleeding at irregular intervals

Exclusion criteria:
Presence of gastrointestinal disorders or any chronic disease requiring long-term treatment Pregnancy or breastfeeding History of immune system–related diseases

Age
From **20 years** old to **55 years** old

Gender
Female

Phase
2

Groups that have been masked

- Data analyser

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, participants are allocated to the intervention groups using permuted block randomization. Blocks of three are generated to include all three study arms (HABES herbal syrup, Golnar capsule, and control group). The allocation sequence is created using a random number table and a standardized clinical trial randomization tool. After enrollment and assignment of a unique study identification number, each participant is allocated to one of the three groups according to the predetermined random sequence. This method is applied to ensure balanced group sizes and to minimize allocation bias.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to differences in the appearance and administration routes of the interventions (herbal syrup and capsules), blinding of participants and treating physicians was not feasible. In addition, the researcher responsible for patient follow-up was aware of group allocation. However, the statistician responsible for data analysis was blinded to treatment assignments, and all data were provided in a coded format. Therefore, the study is conducted as a single-blind clinical trial.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Academic Center for Education, Culture and Research (ACECR), Mashhad, Iran

Street address
Royā Infertility Treatment Center, Academic Center for Education, Culture and Research (ACECR), Shahid Karimi Blvd., Shabnam St., Qom, Iran

City
qom

Province
Ghoum

Postal code
3713189934

Approval date
2025-12-24, 1404/10/03

Ethics committee reference number
IR.ACECR.JDM.REC.1404.008

Health conditions studied

1

Description of health condition studied
Abnormal Uterine Bleeding (Hypermenorrhea / Menorrhagia)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The primary outcome measures include reduction in menstrual bleeding severity assessed by the Pictorial Blood Loss Assessment Chart (PBAC), reduction in the duration of menstrual bleeding, and improvement in quality of life.

Timepoint
Outcome variables are measured at three time points: at baseline before the intervention, at the end of the second menstrual cycle following the intervention, and 60 days after completion of the intervention as a follow-up assessment.

Method of measurement
Bleeding severity is assessed using the Pictorial Blood Loss Assessment Chart (PBAC), bleeding duration is

recorded as the number of menstrual days, quality of life is evaluated using a standardized questionnaire, and laboratory variables are measured by blood tests (CBC, PT, INR, fibrinogen, and serum creatinine).

Secondary outcomes

1

Description

The secondary outcome variables include changes in hematological parameters related to anemia (CBC including hemoglobin, hematocrit, red blood cell count, and platelet count), coagulation parameters (PT, INR, and fibrinogen) to assess hemostatic effects and safety, and changes in serum creatinine levels to evaluate potential treatment-related toxicity.

Timepoint

Measurements of variables are performed at three time points: before the start of the intervention (baseline), at the end of the second menstrual cycle after receiving the intervention, and 60 days after the end of the intervention as a follow-up period.

Method of measurement

Bleeding severity is assessed using the Pictorial Blood Loss Assessment Chart (PBAC), bleeding duration is measured by recording the number of menstrual days, quality of life is evaluated using a standardized questionnaire, and laboratory parameters are assessed through blood tests including CBC, PT, INR, fibrinogen, and serum creatinine.

Intervention groups

1

Description

Intervention group: Grupo de intervención uno: Las pacientes de este grupo reciben cápsulas de Golnar, que contienen Punica granatum y Astragalus gossypinus. La dosis es de tres porciones al día (4 cápsulas por porción; 2 antes y 2 después de las comidas), del cuarto al séptimo día de menstruación, durante dos ciclos menstruales consecutivos.

Category

Treatment - Drugs

2

Description

Intervention group: Grupo de intervención dos: Las pacientes de este grupo reciben jarabe de hierbas Habes, que contiene extractos de cola de caballo, lenteja, zumaque y Golnar. La dosis es de dos cucharadas cada 4 horas, del cuarto al séptimo día de menstruación, durante dos ciclos menstruales consecutivos.

Category

Treatment - Drugs

3

Description

Control group: Grupo de control: Las pacientes de este grupo reciben cápsulas de ácido tranexámico. La dosis diaria es de 2 cápsulas por vía oral, del cuarto al séptimo día de menstruación, durante dos ciclos menstruales consecutivos.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Royā Infertility Center, Academic Center for Education, Culture and Research (ACECR), Qom, Iran

Full name of responsible person
Hoda Fazaeli

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Royā Infertility Treatment Center, Academic Center for Education, Culture and Research (ACECR), Shahid Karimi Blvd., Shabnam St., Qom, Iran

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Email
hodafazaely@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bouali Darou Pharmaceutical Company, Qom, Iran

Full name of responsible person
Hossein Akbari

Street address
Qom, Zaviyeh, Shahid Javad Delazar St., Ahani St., Qods 6th Alley, Iran

City
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3714979356

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Akbari1350.h@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source
Bouali Darou Pharmaceutical Company, Qom, Iran

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Iranian academic center for education culture and research

Full name of responsible person
Hoda Fazaeli

Position
Instructor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

Street address
Royā Infertility Treatment Center, Academic Center for Education, Culture and Research (ACECR), Shahid Karimi Blvd., Shabnam St., Qom, Iran

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Person responsible for scientific inquiries

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Name of organization / entity
Iranian academic center for education culture and research

Full name of responsible person
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Position
Instructor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Data will be reported only in aggregated form without any individual participant identifiers and will include

summary results of the primary and secondary outcomes. Individual participant data (IPD) will not be shared.

When the data will become available and for how long

Data and related documents will be available only after completion of the study and publication of the final results, and solely in aggregated and de-identified form. Individual participant data (IPD) will not be shared at any time.

To whom data/document is available

Access to the study data and related documents will be restricted to members of the research team and authorized regulatory or ethics authorities upon formal request, in accordance with ethical research principles.

Under which criteria data/document could be used

The data and related documents will be used solely for scientific, research, and regulatory purposes related to this study. Data access is permitted only in aggregated and de-identified form and in compliance with ethical principles and confidentiality requirements. Any use beyond the scope of this study will require formal approval from the relevant ethics committee and authorization by the research team.

From where data/document is obtainable

Requests for access to the study data or related documents should be formally submitted to the principal investigator. All requests will be reviewed and approved in accordance with ethical research principles and authorization from the relevant ethics committee.

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

Requests for access to study data or related documents must be submitted in written form to the principal investigator. The request will be reviewed by the research team to assess scientific relevance and compliance with confidentiality requirements. If necessary, the request will be referred to the relevant ethics committee for approval. Upon final approval, limited access will be granted exclusively to aggregated and de-identified data.

Comments