

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Evaluation of a Capsule of Golnar in Dysfunctional Uterine Bleeding and Comparison with Tranexamic acid

Protocol summary

Study aim

Evaluation of effectiveness of Golnar Capsule and its comparison with transaxamic acid

Design

Clinical trial with interventional and control group, parallel groups, double blind, randomized blocks, with sample size of 40 people per group and 3 month study for each person. At first, 90 capsules are given, and for the next two months, a medication is given at the time of the referral of the patient.

Settings and conduct

Arash Hospital, Tehran University of Medical Sciences. In the intervention group, 500 mg Golnar capsule was taken every 8 hours from the first day of menstruation for three consecutive cycles and in the control group 500 mg of tranexamic acid every 8 hours from one to fifth day of Menstruation is prescribed for three consecutive cycles. For blindness in the control group, after the fifth day, placebo capsules are used. Medications can be differentiated only through codes A and B. The person and the researcher are not aware of the concept of codes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women 18-50 years old; Natural pap smear; Regular menstrual cycle; Endometrium thickness less than 10 mm; Severe or prolonged menstruation; Normal Gynology Examination Exclusion criteria: Pregnancy, Decision to pregnancy in the next three months, Lactation, Coagulation disorder, Systsmic diseases; Disorder in FSH and LH; hemoglobin less than 10; endometrial disorder, Uterus cancer ;leiomyoma and fibroids more than 4 cm; endometriosis; Hemoglobinopathy; hormonal drugs, anti-fibrinolytic, IUD; HTN; undisableing menstrual bleeding

Intervention groups

In the intervention group, Golnar capsules 500 mg every 8 hours from the beginning of the menstrual period to the end of the cycle and in the control group, Tranexamic acid, 500 mg, every 8 hours from the first day of the

menstrual period to 5 days, for 3 cycle

Main outcome variables

Menstrual bleeding; Quality of life;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180622040186N1**

Registration date: **2018-06-26, 1397/04/05**

Registration timing: **prospective**

Last update: **2018-06-26, 1397/04/05**

Update count: **0**

Registration date

2018-06-26, 1397/04/05

Registrant information

Name

Somayeh Es.haghee Ashtiany

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7719 1254

Email address

s-eshaghee@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-06, 1397/04/15

Expected recruitment end date

2019-01-05, 1397/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of a Capsule of Golnar in Dysfunctional Uterine Bleeding and Comparison with Tranexamic acid

Public title
The effect of Golnar Capsule (Punica Grantum) in treatment of Abnormal Uterine Bleeding

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Women from 18 years old to 50 years old Normal Pap smear Regular Menstruation Bleeding Endometrial thickness is less than 10 mm Severe Menstruation (According to PBAC: Score>100, 80 cc) or Prolonged Menstruation (More than 7 Days) Normal Gynecological Examination
Exclusion criteria:
 Pregnancy, Plan to become pregnant in the next three months Coagulation Disorders, Systemic Diseases such as Hepatic, Renal, Thyroid, Diabetes and Chronic Inflammatory diseases FSH And LH Disorders Hemoglobin less than 10 Endometrial Disorder, Hyperplasy, Cervical, Uterine and Ovary Cancers Leiomyom and subcutaneous or internal fibroids greater than 4 cm Endometriosis Known Hemoglobinopathy Treatment with Hormonal drugs, Anti-Fibrinolytics and IUD Patients with Hypertension Patients with severe menstrual bleeding without diseases disorders

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Allocation of patients to study groups is done using random block method. Samples were randomly divided into two intervention and control groups based on the random sequence generated by the statistic counselor.

Blinding (investigator's opinion)
Double blinded

Blinding description
The tested drug (Gelnar product) and the control drug (Tranexamic Acid) are identical in terms of appearance and packaging, only through the proprietary A and B codes assigned by a person outside the research group on the box of medication labels are differentiated. The patient and pharmacist prescribing expert are not aware of the concept of codes. Study outcomes of the study are

also known by the researcher who are unaware of the grouping and are blind to the groups and type of medication. During each cycle, the herbal drug is used from the first day of the cycle to the end of the cycle (ie, the patient takes the drug for 3 consecutive months). But the control drug is only used from the beginning of the cycle for 5 days per cycle. For blinding in each group, each patient receives two packets of medicine with codes A1, A2 or B1 and B2. A1 and B1 codes are used from the first day of the cycle for up to 5 days, and codes A2 and B2 are used from the sixth Day cycle to the end of the cycle. In the Gelnar Group, all of 1 and 2 are medicines and in the control group, the numbers of 1 are 1 tranexamic acid and the 2nds are placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Tehran University of Medical Sciences
Street address
 No. 28, Zahra Ave., Niroo Daryae Ave; Resalat Sq
City
 Tehran
Province
 Tehran
Postal code
 1676996913
Approval date
 2018-05-18, 1397/02/28
Ethics committee reference number
 IR.TUMS.VCR.REC.1397.144

Health conditions studied

1

Description of health condition studied
 DUB
ICD-10 code
 N92.1
ICD-10 code description
 Excessive and frequent menstruation with irregular cycle

Primary outcomes

1

Description
 Menstrual bleeding score

Timepoint

One month before and one, two and three months after the intervention

Method of measurement

Pictorial Blood Loss Assessment Chart

2

Description

Quality of Life

Timepoint

One month before the intervention and 3 months after the intervention

Method of measurement

Aberdeen Menorrhagia Questionnaire

Secondary outcomes

1

Description

Age

Timepoint

The beginning of the entry

Method of measurement

Question from sample

2

Description

The numbers of menstruation days

Timepoint

The number of bleeding days in 3 cycles of menstruation

Method of measurement

Day

Intervention groups

1

Description

Intervention group: Persian medicine capsule based on Persian Golnar 500 mg every 8 hours, from the beginning of the menstrual period to the end of the cycle

Category

Treatment - Drugs

2

Description

Control group: Tranexamic Acid Capsule, 500 mg every 8 hours from the first day of menstruation for up to 5 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Hospital

Full name of responsible person

Somayeh Es.haghee Ashtiany

Street address

No. 28, Zahra Ave., Niroo Daryae Ave., Resalat Squ

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Somayeh Es.haghee Ashtiany

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

2

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Somayeh Es.haghee Ashtiany

Position

Assistant

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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

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Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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

Tehran University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

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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

Expression of the procedure and drug used and treatment results

When the data will become available and for how long

Six months after completing the results analysis

To whom data/document is available

Data will be available to researchers working in academic and academic institutions

Under which criteria data/document could be used

Analysis on the data with the permission of the investigating officer is preventable.

From where data/document is obtainable

E-mail, Dr. Somayeh Eshaghee Ashtiany

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

Six months after data analysis

Comments