Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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; undisabling 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)

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+98 21 7719 1254

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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 Inflamatory 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 (Transxamic 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 Daryaee 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 Daryaee 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
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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
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

Person responsible for general inquiries

Contact

Name of organization / entity
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Full name of responsible person
Somayeh Es.haghee Ashtiany
Position
Assistant
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Other areas of specialty/work
Traditional Medicine
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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

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