Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the efficacy of capsule of " Golnar" and Placebo on heavy menstural bleeding in 20- 40 years women: A double- blind randomized clinical trial

Protocol summary

Summary

The aim of the study: A Comparison on the effects of Golnar and Placebo capsules for the excessive bleeding of menstruation This study is a double blind randomized clinical trial.Women are 20 to 40 years who bleed more than 7 days or more than 80 cc per cycle, in case of normal gynecological examination, pelvic ultrasound, Pap smear, Prolactin tests, CBC, TSH, PT PTT, will be studied and in case of having heavy bleeding that requires emergency actions or catching Chronic disease and consumption of specific drugs will be excluded from the study. Intervention in each group will be as follows: 1. Consumption of a 500-mg Golnar capsules, 20 minutes after each meal for 7 days since the beginning of the bloodshed in every menstrual cycle for three menstrual cycles. 2. Consumption of a 500-mg Placebo capsules, 20 minutes after each meal for 7 days since the beginning of the bloodshed in every menstrual cycle for three menstrual cycles. Both groups will be followed for three menstrual cycles. The primary outcome: the volume of bleeding and bleeding time The secondary outcomes: changes in Hb, potential drug side effects and quality of life

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017010231722N1**
Registration date: **2017-04-10, 1396/01/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-04-10, 1396/01/21

Registrant information

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Recruitment status

Recruitment complete

Funding source

Iran university of medical sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of capsule of " Golnar" and Placebo on heavy menstural bleeding in 20- 40 years women: A double- blind randomized clinical trial

Public title

Comparison of the efficacy of capsule of " Golnar" and Placebo on heavy menstural bleeding: A double- blind randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: • Informed written consent of patients • Age 40-20 years • Has bleeding more than 7 days • More than 80 cc blood loss (see Hygam chart) • Endometrial thickness in ultrasound is normal which is equal to or less than 12 mm • Gynecological examination is normal • Pap smear results are normal • Patient has Hb≥11 Exclusion criteria: • Hemoglobin high level of 16 • Bleeding is so severe that emergency measures needed • Plan to become pregnant in the next three months • Catching Systemic or Pelvic inflammatory disease • Catching chronic diseases such as diabetes, lupus and thyroid problems • Catching Organic diseases such as cancer of the Uterus or ovaries or other malignancies • Conjugation of any herbal remedies or certain chemicals that interfere with the study drug or have an impact on menstrual bleeding Such as birth control pills containing estrogen and progesterone or just progestin • Pregnancy and lactation • Catching Known hyperprolactinemia • Catching sub-mucosal or intramural fibroids which are larger than 5 cm • The patient has no wish to consume these types of drugs

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
This is the double-blind study: participants and researchers do not know the type of drug or placebo was administered. Participants by Block Randomization will be divided into two groups.Then the drug and placebo accordance with the table are placed randomly in the hands of participants.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Commitee of Iran University of Medical Science

Street address
Iran University of Medical Science, Besides Milad Tower, Hemmat Highway, Tehran

City
Tehran

Postal code

Approval date
2016-12-27, 1395/10/07

Ethics committee reference number
IR.IUMS.REC.1395.9221309201

Health conditions studied

1

Description of health condition studied
MENSTURAL BLEEDING

ICD-10 code
N92.0

ICD-10 code description
Excessive and frequent menstruation with regular cycle

Primary outcomes

1

Description
bleeding volume

Timepoint
before and 3 month after intervention

Method of measurement
Higam chart(PBAC Questionaire)

2

Description
duration of bleeding

Timepoint
before and 3 month after intervention

Method of measurement
Questionaire

Secondary outcomes

1

Description
Hemoglobin concentration

Timepoint
Before the intervention, and at the end of each menstrual cycle.

Method of measurement
Hemiglobincyanide method, Hemoglobin measuring kit

2

Description
Potential drug side effects

Timepoint
end of intervention

Method of measurement
Questionaire

3

Description
quality of life
Timepoint
Before and the end of intervention
Method of measurement
Menorrhagia Questionaire

Intervention groups

1

Description
Intervention 1.A 500-mg capsules Golnar 20 minutes after each meal for three menstrual cycles during the 7 days will be spent.
Category
Treatment - Drugs

2

Description
Intervention 2. A 500 mg capsules containing bread powder 20 minutes after each meal for three menstrual cycles during the 7 days will be spent.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbar Abadi Hospital in Tehran
Full name of responsible person
Yousefi Fatemeh, Phd student of Traditional medicine
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Akbarabadi Hospital,Molavi Ave., Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for reaserch, Iran University of Medical Science
Full name of responsible person
Roshanak Ghods, Dean of the Faculty of Traditional Medicine
Street address
School of Traditional Medicine, Behesht Street, Vahdat Islami Street, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for reaserch, Iran University of Medical Science
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

2

Sponsor
Name of organization / entity
Research Institute for Islamic and Complementary Medicine/ Iran University of medical science
Full name of responsible person
Fataneh Hashem-Dabaghian, Research Assistant
Street address
Jomhoori st.- Lalezar st.- Pirnia allay- 9
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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
Research Institute for Islamic and Complementary Medicine/ Iran University of medical science
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty