Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of effects of Punica granatum L.(Persian Gulnar) on bleeding in patients with leiomyoma of uterus (in Iranian Traditional Medicine)

Protocol summary

Summary

The general goal: Evaluation of effects of Punica granatum L. (Persian Gulnar) on bleeding in patients with leiomyoma of uterus. Design: Randomized, double-blind, phase II trial. Study population: Patients with heavy menstrual bleeding referred Shahid Beheshti University of Medical Sciences. Target sample size: Based on a pilot study (two groups of 10 people). The main inclusion criteria: 1) Age: 18-50 years. 2) Ultrasound evidence of uterine leiomyoma (submucosal leiomyoma, intramural leiomyoma, subserosal leiomyoma). 3) History of heavy menstrual bleeding based on the patient's complaint. The main exclusion criteria: 1) Indication of uterine surgery (except Caesarean section or cervical conization). 2) Patients receiving progesterone, acetyl salicylic acid anticoagulant. Intervention: Medication (Gulnar syrup) or placebo administration to patient (5 cc three times a day) in menstrual cycle. Intervention Time: Three months (each month 7 days). Study outcomes: Reduction of menstrual bleeding that is evaluated by Pictorial Blood Loss Assessment Chart (PBAC) and improving quality of life that is evaluated by Menorrhagia Questionnaire (MQ).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013120715703N1**
Registration date: **2014-02-12, 1392/11/23**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-02-12, 1392/11/23

Registrant information

Name

Hajar Memarzadeh zavareh

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid beheshti University of Medical Sciences

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effects of Punica granatum L.(Persian Gulnar) on bleeding in patients with leiomyoma of uterus (in Iranian Traditional Medicine)

Public title

Evaluation of effects of Persian Gulnar on bleeding in patients with leiomyoma of uterus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) Age: 18-50 years 2) Ultrasound evidence of uterine leiomyoma (submucosal leiomyoma,

intramural leiomyoma, subserosal leiomyoma). 3) History of abnormal menstrual bleeding based on the patient's complaint. Exclusion Criteria 1) Indication of uterine surgery (except Caesarean section or cervical conization). 2) Patients receiving progesterone, acetyl salicylic acid anticoagulant. 3) Patients with a positive pregnancy test. 4) History of allergy to Persian Gulnar. 5) Known hemoglobinopathies. 6) Known severe coagulation disorder. 7) Patients receiving Anti-fibrinolytic. 8) Hemoglobin below 9.5. 9) Ultrasound evidence of hyperplasia of the endometrium.

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

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Gulnar syrup is made from the aqueous extract of Persian Gulnar.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Velenjak St., Shahid Chamran Highway, Shahid Beheshti university of Medical Sciences.

Street address
Velenjak St., Shahid Chamran Highway, Shahid Beheshti university of Medical Sciences.

City
Tehran

Postal code

Approval date
2013-12-04, 1392/09/13

Ethics committee reference number
1392-1-1-163-1173, 143

Health conditions studied

1

Description of health condition studied
Leiomyoma of uterus

ICD-10 code
D25

ICD-10 code description
Leiomyoma of uterus

Primary outcomes

1

Description
Menstrual blood volume

Timepoint
Before the intervention, weeks 5, 9, 13 after intervention

Method of measurement
Pictorial Blood Loss assessment Chart (PBAC)

2

Description
Quality of life that is evaluated by Menorrhagia Questionnaire (MQ).

Timepoint
Before the intervention, weeks 13 after intervention

Method of measurement
Quality of life that is evaluated by Menorrhagia Questionnaire (MQ).

3

Description
The size of leiomyoma

Timepoint
Before the intervention, weeks 13 after intervention

Method of measurement
ultrasound

Secondary outcomes

1

Description
Side effects

Timepoint
weeks 5, 9, 13 after intervention

Method of measurement
Questionnaire

Intervention groups

1

Description
Medication administration to patient (Persian Gulnar syrup, 5 cc three times a day) in menstrual cycle. Intervention time: Three months (each month 7 days).

Category
Treatment - Drugs

2

Description
Placebo administration to patients in menstrual cycle. (5 cc three times a day) Intervention Time: Two months (each month 7 days).

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
School of Traditional Medicine Traditional Medicine and Materia Medica Research Center Shahid Behesh

Full name of responsible person
Hajar Memarzadeh zavareh

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No.8 Shams Alley, Opposite St Tavanir, Vali Asr Street, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
School of Traditional Medicine Traditional Medicine and Materia Medica Research Center Shahid Behesh

Proportion provided by this source
100

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

Contact

Name of organization / entity
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Full name of responsible person
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Position
ph.D student of Traditional Medicine

Other areas of specialty/work

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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