

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 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

School of Traditional Medicine Traditional Medicine and Materia Medica Research Center Shahid Behesh

Country

Iran (Islamic Republic of)

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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

Street address

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

School of Traditional Medicine Traditional Medicine and Materia Medica Research Center Shahid Behesh

Full name of responsible person

Mojgan Tansaz M.D, Ph.D, Assistant Professor

Street address

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

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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

School of Traditional Medicine Traditional Medicine and Materia Medica Research Center Shahid Behesh

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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Person responsible for scientific inquiries

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Position

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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