

# 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)

##### Phone

+98 21 8877 3521

##### Email address

hajarmemarzadeh@sbmu.ac.ir

##### 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

##### City

Tehran

## 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

##### City

Tehran

#### 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

Hajar Memarzadeh zavareh

#### Position

ph.D student of Traditional Medicine

#### Other areas of specialty/work

#### Street address

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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#### Full name of responsible person

Mojgan Tansaz M.D

#### Position

Traditional medicine specialist, Assistant Professor

#### Other areas of specialty/work

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## Person responsible for updating data

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#### 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*