

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Randomised controled trial of Tranexamic acid and Punica granatum L. in women with menorrhagia

Protocol summary

Summary

This is a double-blind placebo controlled trial to compare the effects of a traditional herbal plant, Persian gulnar (*Punica granatum*), and Tranexamic acid, on the menstrual blood loss volume, quality of life, duration of menses, side effects and acceptance of treatment. 76 women who come to gynecology clinic of Mostafa-Khomeini hospital and some health centers in Tehran, aged 15-45 years old and complaint of heavy menstrual bleeding will be included and randomly allocated to receive Tranexamic, 500mg Q6h, or Persian gulnar, 500mg Q6h on days 1-5 menstrual cycles. The changes in menstrual blood volume and quality of life as well as side effects of drugs will be studied and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138802091641N2**
Registration date: **2010-03-27, 1389/01/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-03-27, 1389/01/07

Registrant information

Name

Azita Goshtasebi

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 3589

Email address

goshtasebi@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Research office of Tarbiat Modares University

Expected recruitment start date

2009-03-05, 1387/12/15

Expected recruitment end date

2010-06-21, 1389/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomised controled trial of Tranexamic acid and
Punica granatum L. in women with menorrhagia

Public title

Clinical trial of Tranexamic acid and medicinal plant of
Persian-gulnar in women with menorrhagia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 20-45 years old, Regular menses, Heavy menstrual bleeding in several cycles, BMI 19-29
Exclusion criteria: Irregular menses or intra menstrual bleeding, Existence of uterine fibroids more than 3cm or other pathologic and iatrogenic causes for abnormal bleeding, Any systemic disease affecting menstrual bleeding, Using hormonal drugs (includes OCPs) or other drugs which influence menstrual bleeding, Having intra uterine device, Pregnancy, Anemia (Hb<10), any regimens for Iron deficiency

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 76

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Medical Department Ethics Comitee of Tarbiat
Modares university

Street address

Medical building1, Tarbiat Modares University, Nasr
bridge.

City

Tehran

Postal code

14117-13116

Approval date

2009-02-02, 1387/11/14

Ethics committee reference number

15021866

Health conditions studied**1****Description of health condition studied**

menorrhagia

ICD-10 code

N92.0

ICD-10 code description

Excessive and frequent menstruation with regular cyc

Primary outcomes**1****Description**

menstrual blood loss

Timepoint

one, two and three cycles after intervention

Method of measurement

by using pictorial blood assessment chart

Secondary outcomes**1****Description**

quality of life

Timepoint

before and after intervention

Method of measurement

by using Aberdeen Menorrhagia Questionnaire

Intervention groups**1****Description**

Intervention group: Persian Gulnar, 500mg, Q6h, days
1-5 of menstrual cycle

Category

Treatment - Drugs

2**Description**

Control group: Tranexamic acid, 500mg, Q6h, days 1-5 of
menstrual cycle

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sardarjanganl healthcare center

Full name of responsible person

Ziba Mazari

Street address

Ordibeheshte Gharbi street, Sardarjanganl Avenue

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research Asisstant of Tarbiat Modares University

Full name of responsible person

Mr. Moosavian

Street address

Nasr bridge, Tarbiat Modares university, Medical
building1

City

Tehran

Grant name**Grant code / Reference number**

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Research Assistant of Tarbiat Modares University

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
Tarbiat Modares University

Full name of responsible person
Dr Azita Goshtasebi

Position
member of Midwifery Faculty

Other areas of specialty/work

Street address
3rd Floor, Medical building3, Tarbiat Modares University, Nasr bridge

City
Tehran

Postal code

Phone
+98 21 8288 3589

Fax

Email
Goshtasebi@modares.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tarbiat Modares University

Full name of responsible person
Dr Azita Goshtasebi

Position
Ph.D/ member of Midwifery Faculty

Other areas of specialty/work

Street address

3rd Floor, Medical building3, Tarbiat Modares University

City
Tehran

Postal code

Phone
+98 21 8288 3589

Fax

Email
goshtasebi@modares.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tarbiat Modares University

Full name of responsible person
Ziba Mazari

Position
Master of Midwifery

Other areas of specialty/work

Street address
no 13, Abuzar st. , Movahed st. , Ahmad-Kashani Av., Shahreziba square

City
Tehran

Postal code
14868

Phone
+98 21 4430 2034

Fax

Email
zibamazarij@yahoo.com

Web page address

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