Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
Sardarjangal healthcare center
Full name of responsible person
Ziba Mazari
Street address
Ordibeheshte Gharbi street, Sardarjangal 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 Asisstant 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