

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison the effectiveness of Plantain seeds and Tranexamic acid in the hemorrhage control of women with Menorrhagia

#### Protocol summary

##### Study aim

Determining the effectiveness of Plantain seeds and Tranexamic acid in the hemorrhage control of women with Menorrhagia

##### Design

In this research, 48 eligible patients with Menorrhagia referring to Ziaeian Hospital were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups.

##### Settings and conduct

After the explanation of the study for people referring to Ziaeian Hospital who have Inclusion criteria, all participants are given consent. At the start of these tests are taken: transvaginal ultrasonography, pap smear, CBC, hormonal tests include TSH, LH, FSH, as well as PT, PTT, INR, BUN, Cr, AST, ALT, and ALP. At the end of the study, CBC, PT, PTT, INR, BUN, Cr, AST, ALT, ALP are repeated for measurement of Hb changes and possible adverse drug reactions. The Pictorial Blood Loss Assessment Chart (PBAC) is used to measure bleeding in two cycles of treatment by the patient. Menorrhagia questionnaire (MQ) is used to measure the quality of life of patients. The pain assessment form is based on the VAS criteria in the two treatment cycles will be completed by the patient. Patients are randomly assigned to one of the groups. Medications are used in both groups for one week from menstruation and two menstruations.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of at least 18 years; Normal geneology examination; Normal pap smear; Endometrial thickness less than 12mm; Severe menstrual bleeding based on PBAC questionnaire Non-Inclusion criteria: significant medical problems; impairment of FSH and LH

##### Intervention groups

Boiled Plantain seeds 10 grams three times a day and half an hour after each meal in a glass of water; Tranexamic acid capsule 500 mg three times daily and

half hour after each meal

##### Main outcome variables

The score of menstrual bleeding severity with Pictorial Bleeding Assessment Chart (PBAC)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160402027170N3**

Registration date: **2017-12-31, 1396/10/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2017-12-31, 1396/10/10**

Update count: **0**

##### Registration date

2017-12-31, 1396/10/10

##### Registrant information

##### Name

Fatemeh Nejatbakhsh

##### Name of organization / entity

medical University Tehran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6675 4151

##### Email address

nejatbakhsh@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research of Tehran university School of Traditional Medicine

##### Expected recruitment start date

2017-12-22, 1396/10/01

##### Expected recruitment end date

2018-12-22, 1397/10/01  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty  
**Scientific title**  
Comparison the effectiveness of Plantain seeds and Tranexamic acid in the hemorrhage control of women with Menorrhagia  
**Public title**  
Effectiveness of Plantain seeds in the Menorrhagia  
**Purpose**  
Treatment  
**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age of at least 18 years Normal gynecology examination Normal Pap Smear Endometrial thickness less than 12mm Severe menstrual bleeding based on PBAC questionnaire  
**Exclusion criteria:**  
Significant medical problems Impairment of FSH and LH  
**Age**  
From **18 years** old  
**Gender**  
Female  
**Phase**  
3  
**Groups that have been masked**  
*No information*  
**Sample size**  
Target sample size: **48**  
**Randomization (investigator's opinion)**  
Randomized  
**Randomization description**  
Allocation to treatment groups was conducted by an independent researcher using a random number sequence, generated with a computer-generated randomization scheme, according to a randomized block design. The block size was six. The randomization list was concealed from the primary researcher who enrolled and assessed participants in sequentially numbered, sealed, opaque envelopes  
**Blinding (investigator's opinion)**  
Not blinded  
**Blinding description**  
**Placebo**  
Not used  
**Assignment**  
Parallel  
**Other design features**

## Secondary Ids

empty

## Ethics committees

1

### Ethics committee

#### Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

#### Street address

Central building of Tehran University of Medical Sciences, near Quds St., Keshavarz Ave. Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

1417733161

#### Approval date

2016-10-09, 1395/07/18

#### Ethics committee reference number

IR.TUMS.VCR.REC.1395.760

## Health conditions studied

1

### Description of health condition studied

Menorrhagia

#### ICD-10 code

N93

#### ICD-10 code description

Abnormal uterine and vaginal bleeding

## Primary outcomes

1

### Description

The score of menstrual bleeding severity with Pictorial Bleeding Assessment Chart (PBAC)

#### Timepoint

Before intervention, One month after the intervention began, two months after the intervention began

#### Method of measurement

Pictorial Bleeding Assessment Chart (PBAC)

## Secondary outcomes

1

### Description

The duration of menstrual bleeding

#### Timepoint

Before intervention, One month after the intervention began, two months after the intervention began

#### Method of measurement

Pictorial Bleeding Assessment Chart (PBAC)

## Intervention groups

1

### Description

Control group: Tranexamic acid capsule manufacturing of

Razak company, 500 mg three times daily and half hour after each meal

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group: boiled Plantain seeds 10 grams three times a day and half an hour after each meal in a glass of water

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Ziaeian Hospital

**Full name of responsible person**

Nejatbakhsh Fatemeh

**Street address**

Ziaeian Hospital, Abouzar St, District 17

**City**

Tehran

**Province**

Tehran

**Postal code**

1366736511

**Phone**

+98 21 5573 8004

**Email**

Nejatbakhsh@tums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Rahimi Roja

**Street address**

No 27, Corner Alley Tabriz, Sarparast Shomali Str, Taleghani Ave

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Phone**

+98 21 8899 0837

**Email**

Rjarahimi@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tehran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Nejatbakhsh Fatemeh

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

No 27, Corner Alley Tabriz, Sarparast Shomali Str, Taleghani Ave

**City**

Tehran

**Province**

Tehran

**Postal code**

1416663361

**Phone**

+98 21 8899 0837

**Fax**

**Email**

Nejatbakhsh@tums.ac.ir

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Nejatbakhsh Fatemeh

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

No 27, Corner Alley Tabriz, Sarparast Shomali Str, Taleghani Ave

**City**

Tehran  
**Province**  
Tehran  
**Postal code**  
1416663361  
**Phone**  
+98 21 8899 0837  
**Fax**  
**Email**  
Nejatbakhsh@tums.ac.ir  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Nejatbakhsh Fatemeh  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Traditional Medicine  
**Street address**  
No 27, Corner Alley Tabriz, Sarparast Shomali Str,  
Taleghani Ave  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1416663361  
**Phone**  
+98 21 8899 0837  
**Email**  
Nejatbakhsh@tums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to

make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

### Title and more details about the data/document

Information about the main outcome after unidentifiable people can be shared

### When the data will become available and for how long

Since print results

### To whom data/document is available

Researchers working in academic and scientific institutions

### Under which criteria data/document could be used

The data can be used by Iranian and non-Iranian researchers in the field of medical sciences in order to perform IPD Meta-analysis and mentioning the name of the corresponding author of the original article in the colleagues of the secondary article. Other analyzes (other statistical models) are not acceptable and researchers are not allowed to use data to write initial studies

### From where data/document is obtainable

Email the corresponding author of the article  
Nejatbakhsh@tums.ac.ir

### What processes are involved for a request to access data/document

The requester sends a letter to the corresponding author of the article and sends a valid certificate of employment in academic and scientific institutions. The author responds within a maximum of 3 weeks and sends the data file

### Comments