Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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+98 21 6675 4151

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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

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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

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Province
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Postal code
1417653761

Phone
+98 21 8899 0837

Email
Rojarahimi@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

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

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Web page address

Person responsible for scientific inquiries

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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