Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect of roasted lentil flour in heavy menstrual bleeding and quality of life in comparison with tranexamic acid in women suffering from menorrhagia

Protocol summary

Summary

Menorrhagia refers to menstrual bleeding more than 80 cc per cycle or a period more than 7 days which half of the cases don't have a pathological cause. In this study, which is a randomized clinical trial, the purpose is to compare the effect of roasted lentil flour as a traditional medicine product with tranexamic acid on the amount of menstrual bleeding. In this study 50 women suffering from menorrhagia aged 18-55 and having at least 100 score in pictorial blood loss and having the inclusion criteria, after initial ultrasonography and lab tests (Hb, PT, PTT, TSH, Prolactin) and satisfaction, randomly divided into intervention and control groups. The intervention group is treated with roasted lentil flour in the form of 10 gram sachets. fasting morning 3 sachets from the beginning of the menstrual bleeding to at last 7 days. The control group is given 500 mg tranexamic acid every 8 hours for a duration of 7 days starting from the first day of menstrual bleeding. Patients during 3 consecutive cycles, take the medication and fill up Pictorial blood assessment chart. At the end, the amount of bleeding, the duration of menstruation and the number of the used pads and also quality of life and HB for both groups have been investigated before and after treatment, and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017072935363N1**
Registration date: **2017-09-19, 1396/06/28**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-09-19, 1396/06/28

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Qom University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of roasted lentil flour in heavy menstrual bleeding and quality of life in comparison with tranexamic acid in women suffering from menorrhagia

Public title

The comparison of the effect of roasted lentil flour and tranexamic acid on the amount of menstrual bleeding and quality of life in women suffering from heavy

menstrual bleeding

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Regular menstrual cycle ; Having a score more than 100 in Pictorial blood assessment chart ; Age between 18 to 55 years old ; No abnormal pap smear or ultrasonography ; No systemic disease (Thyroid, Hyperprolactinemia, Coagulopathy, Diabetes) ; No organic diseases such as uterine or ovary disease or other malignancies ; No consumption of drugs that effect on amount of menstrual bleeding (OCP, ASA) since 2 months ; No pregnancy. Exclusion criteria: Unwilling to continue participation in the study ; Incidence of side-effects requiring special treatment ; The use of any hormonal or contraceptive drug during the study ; Pregnancy.

Age

From **18 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

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

The Ethical Committee of Qom University of Medical Sciences

Street address

Plaque 83, 4th Alley, 1/1 Lane, Safashar Street, Qom

City

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Postal code

87366-37169

Approval date

2017-07-11, 1396/04/20

Ethics committee reference number

IR.MUQ.QEC.1396.43

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 cycle

Primary outcomes

1

Description

Amount of bleeding

Timepoint

One month before, first, second and third month after intervention

Method of measurement

Higam Chart

2

Description

Duration of bleeding

Timepoint

One month before, first, second and third month after intervention

Method of measurement

Higam Chart

Secondary outcomes

1

Description

Quality of life

Timepoint

Before and 3 months after intervention

Method of measurement

Menorrhagia questionnaire

2

Description

Hb level

Timepoint

Before and 3 months after intervention

Method of measurement

Lab test

Intervention groups

1

Description

Intervention group is treated with roasted lentil flour in the form of 10 gram sachets, fasting morning 3 sachets from the beginning of the menstrual bleeding to 7 days.

Category

Treatment - Drugs

2

Description
Control group is given two 250 mg tranexamic acid capsule every 8 hours from the beginning of the menstrual bleeding to 7 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Zafar Clinic
Full name of responsible person
Dr. Shafiei
Street address
Zafar's bulding, 7thTir Street, Shahrdari Square, Qom
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2

Recruitment center
Name of recruitment center
Izadi Hospital
Full name of responsible person
Dr. shafiei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qom University of Medical Sciences
Full name of responsible person
Dr. Majid Asghari
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No 83 Plaque, 4th Alley, 1/1 Alley, Safashahr Street, Qom
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qom University of Medical Sciences
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

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Person responsible for updating data

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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