Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The comparison between Capsella bursa-pastoris and mefenamic acid on bleeding rate, menstrual pain in copper T IUD users in women referred to health centers of Ardabil: a randomized controlled trial

Protocol summary

Summary

Objectives: This study aims to determine the effect of Capsella bursa-pastoris on bleeding rate, menstrual pain in copper T IUD users. Design: Two parallel arm Randomized Controlled Trial Setting and conduct: This study will be conducted in health centers of Ardabil. Eligible women will be randomly assigned into two groups of 45 subjects with block sizes of 4 and 6. A person from research team not involved in the recruitment and assigning participants will generate allocation sequence using a computerized program. Opaque sealed sequentially numbered envelops will be used for allocation concealment. Participants including major eligibility criteria: 90 women aged 18 to 40 years old with menstrual bleeding score higher than 70 according to Higham chart. Interventions: The intervention group will receive Capsella bursa-pastoris capsules 2 g and the control group will receive mefenamic acid capsules 500 mg every 8 hours Main outcome variables: Duration and amount of menstrual bleeding will be assessed by the Higham chart and menstrual pain assessed by the VAS questionnaire, respectively at baseline, 1, 2 and 3 months after starting the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412063027N26**
Registration date: **2015-03-17, 1393/12/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-03-17, 1393/12/26

Registrant information

Name
Fahimeh Sehhatie Shafaie
Name of organization / entity
Tabriz university of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1479 6770
Email address
sehhatief@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between Capsella bursa-pastoris and mefenamic acid on bleeding rate, menstrual pain in copper T IUD users in women referred to health centers of Ardabil: a randomized controlled trial

Public title

The comparison between Capsella bursa-pastoris and mefenamic acid on bleeding rate, menstrual pain in copper T IUD users in women referred to health centers of Ardabil

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Women aged 18 to 40 years old; Passing at least 3 months from IUD insertion; Heavy bleeding in menstrual cycles Due to the IUD insertion; Having regular menstrual cycles before IUD insertion; without disorders of the mefenamic acid consumption; Desire to participation in the study; Being literate
Exclusion Criteria: Known uterine fibroids and other pathologies; Hypothyroid; Hyperthyroid; Coagulation problems and known diabetes.
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
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
Ethics committee of Tabriz University of Medical Sciences
Street address
Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, and East Azerbaijan
City
Tabriz
Postal code
Approval date
2014-11-10, 1393/08/19
Ethics committee reference number
93119

Health conditions studied

1

Description of health condition studied
Uterine Bleeding
ICD-10 code
n93.9
ICD-10 code description
Abnormal Uterine and Vaginal bleeding Unspecified

Primary outcomes

1

Description
Amount of menstrual bleeding
Timepoint
Before intervention, 1, 2 and 3 months after intervention.
Method of measurement
Hygam chart

2

Description
The duration of menstrual bleeding
Timepoint
Before intervention, 1, 2 and 3 months after intervention.
Method of measurement
Hygam chart

3

Description
Severity of Menstrual pain
Timepoint
Before intervention, 1, 2 and 3 months after intervention.
Method of measurement
VAS

Secondary outcomes

1

Description
Female sexual function
Timepoint
Before intervention and 3 months after intervention.
Method of measurement
FSFI questionnaire

2

Description
Adverse events
Timepoint
1, 2 and 3 months after intervention
Method of measurement
Checklist

Intervention groups

1

Description
The intervention group will receive Capsella bursa-pastoris capsule 2 g every 8 hours In the first 7 days of each cycle for 3 Month.
Category
Treatment - Drugs

2

Description
The control group will receive Mefenamic Acid Capsule 500 mg every 8 hours In the first 7 days of each cycle for 3 Month.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ardebil health centers
Full name of responsible person
Hamzepoor Roya
Street address
Nursing and Midwifery Faculty, South Shariati Street
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Rashidi Mohammad Reza
Street address
Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz
City
Tabriz
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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

Contact

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Fahimeh Sehhatie Shafaie
Position
MS on Midwifery
Other areas of specialty/work
Street address
Nursing and Midwifery Faculty, South Shariati Street
City
Tabriz
Postal code
347-51745
Phone
+98 41 1479 6770
Fax
+98 41 1479 6770
Email
sehhatief@tbzmed.ac.ir
Web page address
http://nursing.tbzmed.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Fahimeh Sehhatie Shafaie
Position
MS on Midwifery
Other areas of specialty/work
Street address
Nursing and Midwifery Faculty, South Shariati Street
City
Tabriz
Postal code
Phone
+98 41 1479 6770
Fax
Email
sehhatief@tbzmed.ac.ir
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