

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 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 envelopes 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

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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

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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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