Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigation effect of cumminum cyminum capsule on dysmenorrhea and menstrual bleeding in IUD users.

Protocol summary

Summary

Objective: determine the effect of cumminum cyminum capsule on dysmenorrhea and menstrual bleeding in IUD users. This is a triple-blind, multi-central, randomized clinical trial and cross over study. Method: inclusion criteria: contraceptive method is cupper T380 IUD; 6 months up to 3 years passed after the IUD insertion; with moderate or severe dysmenorrhea assessed by verbal multi-dimensional scoring system; absence of known gastrointestinal, hepatic, thyroid, nephrogenic and cardiovascular disease; absence of NSAIDS and cumin sensitivities. Exclusion criteria: using the capsules not according to medical prescription; taking any kind of medical or herbal analgesic or hormonal drugs during intervention ans removal of IUD. 100 IUD users participate in this study after being informed and signing the written consent. In the first month, pain intensity and menstrual bleeding will be assessed by VAS and Higham chart, then they are randomly allocated in two groups. Each group take their medication 3 times a day for 7 days from the start of their menstrual period. In the control group, women receive two capsules containing 250 mg mefenamic acid. The intervention group women receive two capsules containing 500 mg cumin powder. They receive this drugs for two menstrual period. The capsules in all groups are similar in shape and package. Then each research unit receive the same treatment of the opposite group with the same characteristics. Duration of this stage is two menstrual period. Total sample size will be 200 and VAS and Higham chart will be completed during this five months research period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208106284N4**
Registration date: **2012-08-15, 1391/05/25**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2012-08-15, 1391/05/25

Registrant information

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences,vice chancellor for research

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2012-10-22, 1391/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation effect of cumminum cyminum capsule on dysmenorrhea and menstrual bleeding in IUD users.

Public title

Effect of cumminum cyminum capsule on dysmenorrhea and menstrual bleeding in IUD users.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: contraceptive method is cupper T380 IUD; 6 months up to 3 years passed after the IUD insertion; with moderate or severe dysmenorrhea assessed by verbal multi-dimensional scoring system; absence of known gastrointestinal, hepatic, thyroid, nephrogenic and cardiovascular disease; absence of NSAIDS and cumin sensitivities. Exclusion criteria: using the capsules not according to medical prescription; taking any kind of medical or herbal analgesic or hormonal drugs during intervention ans removal of IUD.

Age

From **15 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

floor6,central organization of university , qods street,keshavarz blv

City

Tehran

Postal code

Approval date

2012-07-01, 1391/04/11

Ethics committee reference number

130/579/91/ɔ

Health conditions studied

1

Description of health condition studied

Secondary dysmenorrhoea in IUD users

ICD-10 code

N94.5

ICD-10 code description

Secondary dysmenorrhoea

2

Description of health condition studied

Menstrual bleeding in IUD users

ICD-10 code

N92

ICD-10 code description

Excessive and frequent menstruation with regular cycle,Excessive and frequent menstruation with irregular cycle

Primary outcomes

1

Description

Severity of dysmenorrhea

Timepoint

At the start of menstrual bleeding,24 hours,48hours,72hours and 7 days after starting menstrual bleeding ,before and after interven tion

Method of measurement

Visual analgue scale (VAS)

2

Description

Menstrual bleeding

Timepoint

During the menstrual bleeding, before and after intervention

Method of measurement

Pictorial blood loss assessment chart(higham chart)

Secondary outcomes

1

Description

Severity of physical symptom of dysmenorrhea

Timepoint

At the end of first month,third month and fifth month of research

Method of measurement

Check list of physical symptom of dysmenorrhea

Intervention groups

1

Description

Cumminum cyminum powder, 500 mg capsule oral, 7days from starting menstrual bleeding , two capsule three times daily

Category

Treatment - Drugs

2

Description
Mefenamic Acid capsules,250 mg capsule,7 days from starting menstrual bleeding,two capsules three times daily,similar in shape and package as same as intervention group

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Hasan mojtaba

Full name of responsible person
Masoomeh Rajabi Naeeni

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2

Recruitment center

Name of recruitment center
24 Mehr Center

Full name of responsible person
Masoomeh Rajabi Naeeni

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5th Navab st., Oaj Shahrak, Hasan Abad, Karaj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences, vice chancellor for recearch

Full name of responsible person
Dr Akbar Fotuhi

Street address
Sixth flloor, Central organization of Tehran University of Medical Sciences, Quds street, Keshavarz blv

City
Tehran

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, vice chancellor for recearch

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

Name of organization / entity
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Position
MSc Midwifery

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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