

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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 copper 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 and 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

###### Name

Maryam Modarres

###### Name of organization / entity

Tehran university of Medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6656 8142

###### Email address

modarres@sina.tums.ac.ir

##### 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 copper 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 and 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**

130/579/91/3

## **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 intervention

#### **Method of measurement**

Visual analogue 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

##### Street address

Shahid Sartip Niaki st., 1st Dehghan Vila, Shahid Beheshti st., Karaj

##### City

Karaj

### 2

#### Recruitment center

##### Name of recruitment center

24 Mehr Center

##### Full name of responsible person

Masoomeh Rajabi Naeeni

##### Street address

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

##### City

Karaj

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences, vice chancellor for research

##### Full name of responsible person

Dr Akbar Fotuhi

##### Street address

Sixth floor, 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 research

##### 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

Tehran University of Medical Sciences

#### Full name of responsible person

Maryam Modarres

#### Position

MSc Midwifery

#### Other areas of specialty/work

#### Street address

Tohid square,East Nysrat street,school of Nursing & Midwifery Tehran University of Medical Sciences

#### City

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#### Postal code

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+98 21 6692 7171

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modarres@sina.tums.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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Tehran University of Medical Sciences

**Full name of responsible person**

Masoomeh Rajabi Naeeni

**Position**

Master Student of Midwifery

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**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*