

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### A comparison between the side effects of low dose combined contraceptive pills and Cyclofem

#### Protocol summary

Iran University of Medical Sciences, Deputy of Research and Technology.

#### Summary

A randomized clinical trial will be performed on 1000 women who are candidate for hormonal contraception. The women will be randomly divided into the 2 groups. In the Cyclofem group, Cyclofem will be injected intramuscularly and will be repeated monthly, and in the second group low dose oral contraceptive pills (LD) will be prescribed. The women will be followed up to one year and the adverse effects of the 2 methods will be compared.

#### Expected recruitment start date

2010-07-01, 1389/04/10

#### Expected recruitment end date

2012-07-01, 1391/04/11

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138903242624N6**

Registration date: **2010-06-14, 1389/03/24**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2010-06-14, 1389/03/24

##### Registrant information

###### Name

Maryam Kashanian

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 7752 3487

###### Email address

maryamka@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

#### Scientific title

A comparison between the side effects of low dose combined contraceptive pills and Cyclofem

#### Public title

A comparison between the side effects of two methods of Contraception

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: non pregnant and married women who are 18-35 years old and are serious for not to be pregnant during the next year and their BMI is in the normal range (19-25). Exclusion criteria: history of breast cancer, endometrial cancer, abnormal uterine bleeding , being smoker, active or chronic liver disease , obstructive jaundice, liver adenoma or carcinoma, liver cirrhosis, thromboembolic disorders, heart disease, stroke, diabetes, hypertension, recurrent headache or dizziness, history of depression or anxiety, breast feeding, dislipidemia, any systemic disorder or any drug use for systemic disorders, AUB , Oligomenorhea.

#### Age

From **18 years** old to **35 years** old

#### Gender

Female

#### Phase

2-3

### Groups that have been masked

No information

### Sample size

Target sample size: 1000

### 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

Iran University of Medical Sciences

##### Street address

Hemmat Highway, Chamran Cross.

##### City

Tehran

##### Postal code

#### Approval date

2010-07-07, 1389/04/16

#### Ethics committee reference number

1729909

## Health conditions studied

### 1

#### Description of health condition studied

Contraception

#### ICD-10 code

Z30.0

#### ICD-10 code description

General counselling and advice on contraception

## Primary outcomes

### 1

#### Description

adverse effects

#### Timepoint

1-3-6-12 months

#### Method of measurement

questionnaire

## Secondary outcomes

### 1

#### Description

The frequency of discontinuation of contraception

#### Timepoint

1-3-6-12 months

#### Method of measurement

Questionnaire

## Intervention groups

### 1

#### Description

low dose contraceptive pills (LD) 1 pill daily for 21 days/month and starting again 7 days later

#### Category

Treatment - Drugs

### 2

#### Description

Cyclofem, 1 injection monthly

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tehran Public health centers

##### Full name of responsible person

##### Street address

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences, Deputy of Research and Technology

##### Full name of responsible person

Dr. Motavallian

##### Street address

Hemmat Highway, Chamran Cross.

##### City

Tehran

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Iran University of Medical Sciences, Deputy of Research

and Technology

**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**

Iran University of Medical Sciences

**Full name of responsible person**

Dr. Maryam Kashanian

**Position**

MD, Associate professor

**Other areas of specialty/work**

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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*