Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

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.

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

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Maryam Kashanian
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

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

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

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

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Position

MD, Associate professor

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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