Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Oral Contraceptive Pills on Disease Activity in Women with Rheumatoid Arthritis, Tehran, 2010-2011

Protocol summary

Summary

Overall objective: To determine the effect of oral contraceptives on disease activity in women with rheumatoid arthritis referred to selected rheumatology centers in Tehran. Specific objectives: 1. Comparison of disease activity at enrollment and after 8 weeks in case group 2. Comparison of disease activity at enrollment and two months after that in control group 3. Comparison of disease activity between two groups after 8 weeks. Design: Randomized controlled clinical trial Method: consult with qualified women in the study, informed consent to participate in the study, randomly allocated in case (receiving oral contraceptive pills group) and control groups, determination of rheumatoid arthritis disease activity at the beginning of the study in two groups, administered intermittently oral contraceptive pills for 8 weeks in case group with onset of the first menstrual cycle (3 weeks administration and one week off and then start again the second box at the fifth week) and routine follow up in the control group, determination of disease activity in both groups again, compared The two groups regarding to study specific goals. Samples: one hundred women of reproductive age (50 people in case group and 50 people in control group) who married and want to use oral contraceptives and are receiving medical treatment for rheumatoid arthritis disease and also didn't use oral contraceptive pills during past 6 months. Interventions: Administration of oral contraceptives for 8 weeks of intermittent in case group and no intervention in control group. Consequences: disease activity of rheumatoid arthritis

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904224364N1**
Registration date: **2011-07-24, 1390/05/02**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2011-07-24, 1390/05/02

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Tehran University of Medical Sciences

Expected recruitment start date

2010-08-06, 1389/05/15

Expected recruitment end date

2010-11-22, 1389/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Oral Contraceptive Pills on Disease Activity in Women with Rheumatoid Arthritis, Tehran, 2010-2011

Public title

The Effect of Oral Contraceptive Pills on Disease Activity in Women with Rheumatoid Arthritis, Tehran, 2010-2011

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : healthy women without any other physical or mental diseases ; oral contraception contraindications; no changes in patient's medication regimen during last three monts; no decision for pregnancy; suspicion of pregnancy; giving medical treatment,no use OCPs during last 6 months - Exclusion criteria of the study are: Complications detection such as severe nausea and vomiting; because of pills; high risk patients for OCPs

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Ethics committee of Nursing & Midwifery Faculty of Tehran University of Medical Sciences

Street address

Faculty of Nursing and Midwifery, Touhid Sq

City

Tehran

Postal code

4798/19395

Approval date

0655-12-31, 35/01/-78

Ethics committee reference number

1744411

Health conditions studied

1

Description of health condition studied

Rheumatoid Arthritis

ICD-10 code

M06.9

ICD-10 code description

Rheumatoid arthritis, unspecified

Primary outcomes

1

Description

Rheumatoid Arthritis disease activity

Timepoint

Befor and 2 months after study

Method of measurement

Instrument DAS-28

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention: Low dose oral Contraceptives Pills administration as routine for 2 cycles in order to contraceptive purpose

Category

Prevention

2

Description

Control: Without any intervention

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology Centers

Full name of responsible person

Mehri Kalhor

Street address

Faculty of Nursing and Midwifery of Tehran, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotoohi
Street address
Vice chancellor for research Tehran University of Medical Sciences, Keshavarz Building, Keshavarz Blv, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research Tehran 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

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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