Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison between metformine and mejestrol for the treatment of endometrial hyperplasia

Protocol summary

Summary

Objective:comparison between metformine and mejestrol for the treatment of simple endometrial hyperplasia. Design:randomized clinical trial. setting and conduct:in one group metformine and in the other group mejestrol will be prescribed for 12 weeks. Participants:Inclusion criteria: ultrasound which confirms endometrial thickening and simple endometrial hyperplasia without atypia in endometrial sampling. exclusion criteria: history of intolerance to metformine or mejestrol; using metformine during previous 6 months; history of hepatic or renal disorders; plasma glucose of less than 60 mg/dl or more than 200 mg/dl ; current using of any medication, any gynecologic neoplasia; using any kind of hormones. Interventions:in one group metformine and in the other group mejestrol will be prescribed for 12 weeks. Main outcome:improvement in endometrial hyperplasia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506252624N18**
Registration date: **2016-03-22, 1395/01/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-03-22, 1395/01/03

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

investigator

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between metformine and mejestrol for the treatment of endometrial hyperplasia

Public title

Treatment of endometrial hyperplasia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ultrasound which confirms endometrial thickening and simple endometrial hyperplasia without atypia in endometrial sampling. exclusion criteria: history of intolerance to metformine or mejestrol; using metformine during previous 6 months; history of hepatic or renal disorders; plasma glucose of less than 60 mg/dl or more than 200 mg/dl ; current using of any medication, any gynecologic neoplasia; using any kind of hormones.

Age

No age limit

Gender
Female

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomization was performed as stratified block randomization.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran University of Medical Sciences
Street address
No 9, Mostaghimi Alley, Khajeh Nasir Toosi Avenue, postcode 16117, Tehran, Iran.
City
Tehran
Postal code
16117
Approval date
2014-09-15, 1393/06/24
Ethics committee reference number
93/2920 /105/د

Health conditions studied

1

Description of health condition studied
Other noninflammatory disorders of uterus, except cervix
ICD-10 code
N85
ICD-10 code description
Other noninflammatory disorders of uterus, except cervix

2

Description of health condition studied
Endometrial glandular hyperplasia
ICD-10 code
N85.0
ICD-10 code description
Endometrial glandular hyperplasia

3

Description of health condition studied
Endometrial adenomatous hyperplasia
ICD-10 code
N85.1
ICD-10 code description
Endometrial adenomatous hyperplasia

Primary outcomes

1

Description
Endometrial hyperplasia
Timepoint
3 months after treatment.
Method of measurement
endometrial sampling

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: administration of metformine, 1000 miligram daily for 4 weeks followed by 1500 miligram daily for 8 weeks.
Category
Treatment - Drugs

2

Description
Intervention group 2: administration of mejestrol, 40 miligram daily for 12 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbarabadi Teaching Hospital
Full name of responsible person
Maryam Kashanian
Street address
Molavi avenue, Molavi Cross.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research ,Iran University of Medical Sciences.
Full name of responsible person
Dr Seyed Ali Javad Mousavi
Street address
Hemmat High way, 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
Vice chancellor for research ,Iran 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

Contact
Name of organization / entity
Iran University of Medical Sciences
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Maryam Kashanian
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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