Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison the effect of Metformin and Chromium picolinate on pregnancy rate in Clomiphene Citrate-Resistant Polycystic Ovary Patients

Protocol summary

Summary
Objectives: To compare pregnancy rate between the chromium picolinate group and metformin group in clomiphen citrate resistant PCOS patients. Methods: This was a randomized clinical trial being performed at university affiliated clinices including 92 women with clomiphen citrate-resistant PCOS who were randomly assigned to receive chromium picolinate (200µg daily) or metformin (1500mg daily) for 3 months.Pregnancy rate after 3 months was our major outcome. Anthropometric and hormonal profile were measured and compared before and after treatment. Inclusion criteria: poly cystic ovaries;clomiphene resistant ;infertile. Exclusion criteria:any medical disease.

General information

Acronym
non
IRCT registration information
IRCT registration number: **IRCT201203139281N1**
Registration date: **2012-06-14, 1391/03/25**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2012-06-14, 1391/03/25

Registrant information
Name
Sedigheh Amooee
Name of organization / entity
Shiraz University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source
Shiraz University of Medical Science

Expected recruitment start date
2009-01-01, 1387/10/12
Expected recruitment end date
2011-01-01, 1389/10/11
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of Metformin and Chromium picolinate on pregnancy rate in Clomiphene Citrate-Resistant Polycystic Ovary Patients

Public title
Comparison of two drug for poly cystic ovary
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: poly cystic ovaries;clomiphene resistant ;infertile. Exclusion .criteria:any medical disease like diabetes;Cushing’s syndrome; hyperprolactinemia ; thyroid disease ; other endocrinopathies ; oral contraceptives (OCPs); any medications that interfere with lipid metabolism.
Age
From **15 years** old to **40 years** old
Gender
Female

Phase
N/A

Groups that have been masked
No information
Sample size
Target sample size: **92**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
shiraz university of medical science ,ethics committee
Street address
Zand street
City
Shiraz
Postal code
713451975
Approval date
2012-03-05, 1390/12/15
Ethics committee reference number
5390

Health conditions studied

1

Description of health condition studied
Female infertility
ICD-10 code
N97.0
ICD-10 code description
Female infertility associated with anovulation

Primary outcomes

1

Description
pregnancy rate
Timepoint
3 months after starting
Method of measurement
pregnancy test

Secondary outcomes

1

Description
pateint telorance testestron
Timepoint
each month
Method of measurement
lab data questioare

Intervention groups

1

Description
In first group patients take1500mg/day metformine in 3 divided dosage
Category
Treatment - Drugs

2

Description
In second group patients take chromium picolinate200mcg /day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
infertility center
Full name of responsible person
Street address
zand avenue
City
shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
vice chanceller ,Dr.Gholam reza Hatam
Street address
Zand avenue
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Shiraz 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

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Full name of responsible person

Sedigheh Amooee

Position

Assistant professor

Other areas of specialty/work

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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