Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of clomiphen citrate in pcos patients underging Intra uterine Insemanation cycles.

Protocol summary

Summary

The Overall Objective : Effect of clomiphene citrate for prevention of premature LH surge in infertile women with poly cystic ovary syndrome undergoing intra uterine insemination(IUI). Specific objectives: Compare the number of mature follicles , endometrial thickness ,pregnancy rate ,miscarriage rate and ongoing pregnancy rate in infertile women undergoing intra uterine insemination(IUI), with receiving clomiphene citrate and control group. Material and method: According to consult with statistics, 162 patients were divided to 2 groups, case and control .Patients with history of at least one year infertility ,who came to infertility clinic of mother and child hospital of shiraz with a history of clomiphene citrate resistance for 3 cycles were randomized and divided to two groups of 81 patients. After taking testimonial form , study was started. In this study 162 patients who had 2 or more including factors for ESHRE criteria for polycystic ovary syndrome with a history of at least one year infertility and 3 cycles clomiphene citrate resisitance who were candided for IUI, were divided to two groups randomaly due to table of random statistics numbers . (ESHRE/ASRM criteria for poly cystic ovary syndrome :chronic anovulation ,clinical or biochemical evidence of androgen excess and polycystic appearing ovaries on trans vaginal sonography)complications such as probability of OHSS, no response to gonadotropin therapy or not completing the course of treatment ,are the most excluding criteria.During study On the third day of the menstrual cycle , a basal vaginal sonography and a blood sample for hormonal assays were performed .Recombinal FSH (Gonal –F –serono) was injected subcutaneosly in a dosage of 75 IU/day from the 3rd day of the cycle to the day of the HCG injection those who were assigned to clomiphene citrate group ,receive 150 mg/day of clomiphene citrate (REZA K –Tehran) from the 8th to the they of HCG injection and those who were assigned to control group ,received nothing except r-Fsh..

Transvaginal sonography will be performed on the day of 11th of the cycle ,and rFSH will be contined till at least two dominant follicle with size of >18 mm will be seen then 10000IU of HCG will be injected intramusculary if serum E2 was <2000 pg/ml. The Endometrial thickness(ET) and serum LH, will be measured at the same day of hcg injection . Intra uterin insemination (IUI) Will be performed 36 hours after HCG administration. And B.HCG will be checked if the patient experience one week missed period . But pregnancy will be documented by transvaginal sonography at 6-7 weeks of gestation. And then data analysis will be done .At last 2 groups of case and control will be compared by number of mature follicles ,endometrial thickness, estradiol level on the day of HCG injection , premature LH surge (serum LH>10 IU /ML) chemical and clinical pregnancy rate,and abortion rate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT20160220010210N4**
Registration date: **2016-06-15, 1395/03/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-06-15, 1395/03/26

Registrant information

Name

Afsun Zarei

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status
Recruitment complete
Funding source
vice chancellor for research,Shiraz university of medical aciences

Expected recruitment start date
2012-07-31, 1391/05/10
Expected recruitment end date
2013-12-22, 1392/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of clomiphen citrate in pcos patients underging Intra uterine Insemanation cycles.

Public title
Effect of clomiphene citrate for prevention of premature LH surge in Intra uterine Insemanation cycles.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Patients who have 2 or more of including factors for ESHRE criteria for polycystic ovary synrdrome and have history of at least one year infertility and 3 cycles clomiphene citrate resistance؛Diagnosis criteria for PCOs according to ESHRE-ASRM(ESHRE/ASRM criteria for PCOS:chronic anovulation ,clinical or biochemical evidence of androgen excess and polycystic appearing ovaries on trans vaginal sonography) Exclusion criteria : Collateral effect such as probability of no response to the treatment، OHSS gonadotropin syndrome؛ lake of patient collaboration in performing drug cycle
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **162**
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 shiraz University of Medical Sciences
Street address
Shiraz University of Medical Science،zand street
City
Shiraz
Postal code
Approval date
2012-07-26, 1391/05/05
Ethics committee reference number
ct-p-91-3052

Health conditions studied

1

Description of health condition studied
The effect of clomiphene citrate in prevention of premature LH surge in PCOS patients underging IUI
ICD-10 code
N97.0
ICD-10 code description
Female infertility associated with anovulation

Primary outcomes

1

Description
Premature LH surge
Timepoint
On the day of HCG injection
Method of measurement
measurement of serum LH level of laboratory

2

Description
Number of nature follicles
Timepoint
on the day of HCG injection
Method of measurement
measurement of number of mature follicles by trans vaginal sonography (TVS).

3

Description
Amount of serum esteradiol(E2) level
Timepoint

On the day of HCG injection

Method of measurement

Measurement of serum E2 level in lab

4

Description

Endometrial thickness

Timepoint

on the day of HCG injection

Method of measurement

measurement of endometrial thickness by trans vaginal sonography (TVS).

Secondary outcomes

1

Description

chemical or clinical pregnancy

Timepoint

One week after retard of menstrual time ,at the 6th -7th week of gestation.

Method of measurement

trans vaginal sonography

Intervention groups

1

Description

In clomiphene citrate group recombinant FSH (Gonal –F ,serono) 75 IU /day from 2nd day of cycle till the day of HCG injection and clomiphene citrate 150 mg/day (REZA K –Tehran) from the 8th to the day of HCG injection was prescribed.

Category

Treatment - Drugs

2

Description

In the control group only recombinant FSH (Gonal –F ,serono) 75 IU /day from 2nd day of cycle till the day of HCG injection was prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghadir Mother & child Hospital

Full name of responsible person

Mahshid Alborzi

Street address

Ghadir Mother & child Hospital- Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research , Shiraz University of Medical Sciences

Full name of responsible person

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences،Zand Street

City

Shiraz

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 , 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

Shiraz University of Medical Sciences

Full name of responsible person

Mahshid Alborzi

Position

Infertility Fellowship

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Shiraz University of Medical Sciences
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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