Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of Clomiphene Citrate and Letrozole in pregnancy rate after intrauterine insemination

Protocol summary

Summary

Type of study: prospective randomized clinical trial. Population studied: infertile women between 20 and 35 years old without underlying disease. Sample size: 65. The patients are divided into two groups. The intervention group is given clomiphene citrate tablet and control group is given Letrozole tablet. Both groups were administered gonadotropin. Then in the ultrasound series when the number of follicles 22-18 milimeter to 5-2 number were administered one ampoule hCG (the amount of ten thousand units). In this day, was measured the number of follicles larger than 14mm and Endometrial thickness in trans vaginal sonography. In follow up, the two groups are compared clinical and chemical pregnancy rates and complications of gonadotropins.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106256871N2**
Registration date: **2012-08-08, 1391/05/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-08-08, 1391/05/18

Registrant information

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Shahnaz Ahmadi
Name of organization / entity
Bushehr University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Management Research of Bushehr University of Medical Sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-05-05, 1390/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Clomiphene Citrate and Letrozole in pregnancy rate after intrauterine insemination

Public title

The effect of inducer drugs knowing ovulation fertility after IUI procedure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: duration of infertility for more than a year, less than 35 years of age, ensuring the openness of the fallopian tubes at laparoscopy or hysterosonography and attended at least 10 million sperm per milliliter of semen. Exclusion criteria: age greater than 35 years, moderate and severe endometriosis, basal serum FSH> 10mIU/ml, Hyprprvlaktynvma, hyperthyroidism, Cushing's syndrome, heart and liver disorders, and nonclassic Congenital adrenal hyperplasia, drugs and other drugs Zddyabt hormonal, organic pelvic diseases, previous pelvic Vjrahy

Age
From **20 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **65**
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
Bushehr University of Medical Sciences
Street address
Bushehr.Pardis's Site of Bushehr University of Medical Sciences , Research Management
City
Bushehr
Postal code
Approval date
2010-12-02, 1389/09/11
Ethics committee reference number
B-9013-2

Health conditions studied

1

Description of health condition studied
Female infertility associated with male factors
ICD-10 code
N97.4
ICD-10 code description
Female infertility associated with male factors

Primary outcomes

1

Description
The number of follicles larger than 14milimeter
Timepoint
day of human chrionic gonadotropin administration
Method of measurement
Trans Vaginal Sonography

2

Description
Endometrial thickness
Timepoint
Day of administration hCG
Method of measurement
Trans Vaginal Sonography

Secondary outcomes

1

Description
multiple pregnancy
Timepoint
14 days after confirmation of chemical pregnancy
Method of measurement
Trans Vaginal Sonography

2

Description
Ovarian Hyper Stimulation Syndrom
Timepoint
after confirmation pregnancy
Method of measurement
History and Phisical exam and symptoms

3

Description
Chemical pregnancy
Timepoint
16 day after administration of human chorionic gonadotropin
Method of measurement
β-hCG

4

Description
Clinical Pregnancy
Timepoint
14 day after confirmation of chemical pregnancy
Method of measurement
Trans Vaginal Sonography

Intervention groups

1

Description
Letrozole group(group A) is administrated tablet Letrozole 10miligram,daily,orally,from 3th-7th day of menstural cycle and two gonadotropin in 8th day and one gonadotropin in 9th day of menstural cycle.and

when follicles 18-22mm to 2-5,one hCG ampoule (10000 units)was administrated.

Category

Treatment - Drugs

2

Description

Clomiphene Citrate group(group B) is administrated tab CC 100 mg,daily,orally,from 3th-7th day of menstural cycle and two gonadotropins in 8th day and one gonadotropin in 9th day of menstural cycle.Amp hCG was administrated simillar to group A.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Abolfazl women`s Clinic

Full name of responsible person

Dr. Shahnaz Ahmadi

Street address

Clinic Abolfazl- field hospital -Bushehr

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Management Research of Bushehr University of Medical Sciences

Full name of responsible person

Dr. Shahnaz Ahmadi

Street address

Management Research, Pardis's site of Bushehr University of Medical Sciences, Bushehr

City

Bushehr

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Management Research of Bushehr 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

Bushehr University of Medical Science

Full name of responsible person

Dr. Shahnaz Ahmadi

Position

Assistant Professor

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Person responsible for scientific inquiries

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Person responsible for updating data

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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