

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

The comparative study of Clomiphene citrate and short course Anastrozole in intrauterine insemination cycles

Protocol summary

Summary

In this study 60 infertile patients referred to infertility research center of Motazedi hospital are studied. All the women should have at least 12 months of unprotected coitus. They undergo a fecundity survey including medical record, physical examination and basal vaginal sonography in the third day of menstruation cycle. Other parameters such as mid luteal phase serum progesterone level, semen analysis of the partner, third day serum FSH and LH level are measured and hysterosalpingography are done to exclude tubal factor. The patients are considered to have unexplained infertility when there are no other etiologies for infertility and these women are entered the study. In the third day of the cycle, basal TVUS is done to study uterine and adnexa and to measure the endometrial thickness. In control group 100 mg of Clomiphene citrate is given in Single dose for 5 days parenterally from days 3-7 of menstruation cycle and in case group Anastrozole tab 1mg will be given in single dose for 3 days parenterally from days 3-5 menstruation cycle. In both groups injectable HMG (gonal F/IM/ Serono ...) will be prescribed from days 6-9 with constant dose of 75 units. In the 9th of the cycle a second vaginal sonography is done and in case of inappropriate response (follicle less than 17mm in diameter) injectable HMG is continued till a mature follicle is obtained.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810193028N1**
Registration date: **2009-05-22, 1388/03/01**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-05-22, 1388/03/01

Registrant information

Name

Taravat Fakheri

Name of organization / entity

Maternity Research center, Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 6309

Email address

tfakheri@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2009-05-22, 1388/03/01

Expected recruitment end date

2010-04-21, 1389/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparative study of Clomiphene citrate and short course Anastrozole in intrauterine insemination cycles

Public title

A comparative study of Clomiphene citrate and short course Anastrozole in intrauterine insemination cycles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) to have at least 12 months of infertility; 2) unexplainable infertility; 3) regular period cycles between 21 to 35 days. Exclusion Criteria: 1) women younger than 18 and older than 38 years old; 2) anovulation; 3) prior ART cycles; 4) systemic diseases such as endometriosis, persistent ovarian cyst and malignancies of breast, ovary and uterine. Basic alternatives such as age and BMI are measured and both groups regarding the alternatives will be matched.

Age

From **18 years** old to **38 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

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**

Kermanshah University of Medical Sciences

Street address

Obs & Gynecology department, Imam Reza Hospital,
Parastar Blvd

City

Kermanshah

Postal code

67144-15333

Approval date

empty

Ethics committee reference number

7/420/2613/پ

Health conditions studied**1****Description of health condition studied**

Unexplained infertile women undergoing IUI treatment

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes**1****Description**

Numbers and size of adult follicles after one treatment cycle

Timepoint

In every stimulation cycle , in the Ninth day of cycle

Method of measurement

By means of vaginal sonography

Secondary outcomes**1****Description**

Thickness of endometrium after a period of treatment

Timepoint

In every ovulatory cycle in the ninth day of cycle

Method of measurement

By means of vaginal sonography

Intervention groups**1****Description**

In case group: Anastrozole tablets 1 mg / once daily/ for three days, from days3-5 of menstrual cycle and followed by gonadotropines from days 6-8

Category

Treatment - Drugs

2**Description**

In control group: Clomiphene citrate tablets 50 mg orally, two tablets per day, from days 3-7 and followed by gonadotropins from days 6-8

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Infertility Research Center of Motzedi Hospital

Full name of responsible person

Dr. Taravat Fakhri

Street address**City**

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences (KUMS)

Full name of responsible person

Dr. Farid Najafi

Street address

Kermanshah University of Medical Sciences (KUMS).

City

Kermanshah

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kermanshah University of Medical Sciences (KUMS)

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**

Kermanshah University of Medical Sciences (KUMS)

Full name of responsible person

Dr, Taravat Fakheri

Position

Assistant Professor

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Kermanshah University of Medical Sciences (KUMS)

Full name of responsible person

Dr.Salma Hosseini

Position

Resident

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Person responsible for updating data

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Kermanshah University of Medical Sciences (KUMS)

Full name of responsible person

Sara Daei Chin

Position

Obstetrics (BCs) Of Maternity Research Center

Other areas of specialty/work**Street address**

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Hospital,Parastar Blvd,Sorkheh Lyjeh,Kermanshah
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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