

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Evaluation of the effect of dopamine D2 antagonist on the success of invitro fertilization in poor responders

Protocol summary

Summary

Compare oocyte counts, mature oocyte count, fertilization rate, cleavage rate, valid embryo count, clinical pregnancy rate, implantation rate, spontaneous abortion rate, in IVF cycle in poor responders that received dopamine D2 antagonist and control group. 50 poor responder patients according to Bologna criteria after taking testimonial form divided to 2 groups, case and control. (Bologna criteria: previous treatment using conventional protocols that yielded less than 3 oocytes, AMH < 0.5-1.1 ng/ml or AFC < 5-7 Follicles, age over 40 years or any risk factor that decrease the ovarian reserve) side effects are most important excluding factors. First group received metoclopramide 1 Tab (10mg) 4 times in a day (pre prandial and at the bed time) for 4 weeks and then start IVF cycle when continue the drug. IVF cycle start as antagonist protocol with gonadotropins 450 IU/day, at last pick up done after triggering with HCG. Drugs, Metoclopramide or placebo have the same packages but special codes. Each person including the study does not know which pocket is Metoclopramide or placebo and our study is completely double-blind. After taking all data, code of drug pockets will be opened and the conclusion will be explained according to it. At last 2 groups of case and control will be compared by number and quality of oocytes that retrieved and fertilization rate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015082622206N2**

Registration date: **2016-06-19, 1395/03/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-19, 1395/03/30

Registrant information

Name

Alamtaj Samsami

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellery for Medical Sciences research of Shiraz University

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of dopamine D2 antagonist on the success of invitro fertilization in poor responders

Public title

Effect of Metoclopramide on fertility in women with loss of ovarian reserve

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: previous treatment using conventional protocols that yield less than 3 oocytes, abnormal ovarian reserve tests as AMH<0.5-1. 1ng/ml or AFC <5-7 Follicles, age over 40 years or any other risk factor that decrease the ovarian reserve such as previous ovarian surgery, genetic problems, chemotherapy, radiotherapy and autoimmune disease, having 2 or more of above factors (Bologna criteria). Exclusion criteria: not have above factors, no agreement of patient, she can not complete the course of treatment, become OHSS. (ovarian hyperstimulation syndrome)

Age

From **40 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee Shiraz University Of Medical Science

Street address

Building of Shiraz University Of Medical Science, Zand Street, Shiraz

City

Shiraz

Postal code**Approval date**

2015-07-12, 1394/04/21

Ethics committee reference number

IR.sums.rec.1394.70

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

patients with poor ovarian response

ICD-10 code

(P00-P96)

ICD-10 code description

Certain conditions originating in the perinatal period

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

Quality and number of ovum and embryo have received in each IVF cycle.

Timepoint

On day of ovum pick up and embryo transfer

Method of measurement

Measuring number and quality of oocyte on the day of pick up in lab by embryologist under microscope (GV,MI,MII) and quality of embryo also by the same embryologist according to kind of cell division (grade I,II,III,IV)

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

Clinical pregnancy or spontaneous abortion

Timepoint

7-12 weeks after embryo transferring

Method of measurement

Serum BHCG and TVS

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

Interventional group: Metoclopramide 10 mg 4 times/day (pre prandial and at the bed side) The drug started 4 weeks before starting IVF cycle and continued till triggering with HCG.

Category

Treatment - Drugs

2**Description**

Control group: similar placebo effect drugs with the same dose. (pre prandial and at the bed side) The drug started 4 weeks before starting IVF cycle and continued till triggering with HCG.

Category

Placebo

Recruitment centers**1****Recruitment center**

Name of recruitment center

Shiraz Ghadir Mother and Child Subspecialized
Hospital

Full name of responsible person

Street address

City

Shiraz

Email

Pardis.bakhshaie287@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Alamtaj Samsami

Position

Professor

Other areas of specialty/work

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Medical Sciences Research of
Shiraz University

Full name of responsible person

Dr Syed Baser Hashemi

Street address

7th Floor dean of research, Building of University Of
Medical Science, Zand Street, Shiraz , Fars , Iran,
Islamic Republic

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 Medical Sciences Research of Shiraz
University

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

Dr Pardis Bakhshaie

Position

Fellowship Infertility

Other areas of specialty/work

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Person responsible for updating data

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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