

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of prednisolone on ICSI outcomes in women with immunological recurrent implantation failure

Protocol summary

Summary

In spite of many researches in this field, more than 50% of transferred embryos don't implant in IVF/ICSI cycles. there are many causes of implantation failure : the most important of them are genetic, anatomic, immunologic,...and there are multiple treatments for them. recurrent implantation failure(RIF) is supposed when there are at least 2 unsuccessful embryo transferred cycles(fresh or freeze) with good quality embryos if female age is less than 40 years. immunological factors don't have fixed definition and treatments. there are some treatment such as prednisolone, IVIG, Intralipid,...and there are not any proved agreement about them. so we designed a double blind randomized clinical trial on 220 infertile women with RIF with immunological factors such as ANA+, ds DNA+, Antithyroid antibodies(Anti TG, Anti TPO)+, CD markers(CD16, CD56 or CD5, CD19)+ and we divided them randomly in two groups. they receive prednisolone 10 mg daily or placebo of prednisolone about 1.5 months before embryo transfer and continue drugs until 12 weeks of pregnancy in women who get pregnant and evaluate pregnancy rate, implantation rate and ongoing pregnancy rate until 12 weeks. treatment with prednisolone seem to improve ICSI outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091618662N2**
Registration date: **2016-09-19, 1395/06/29**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-09-19, 1395/06/29

Registrant information

Name

Farnaz Fatemi

Name of organization / entity

Avicenna Research Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2020

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Recruitment status

Recruitment complete

Funding source

Avicenna Infertility Clinic

Expected recruitment start date

2016-09-24, 1395/07/03

Expected recruitment end date

2018-03-24, 1397/01/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of prednisolone on ICSI outcomes in women with immunological recurrent implantation failure

Public title

Efficacy of Prednisolone on ICSI outcomes in a group of women with recurrent implantation failure

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion Criteria: 1- At least 2 unsuccessful IVF/ICSI cycles 2- Grade A or AB of transferred embryos in previous cycles and at least 6 embryos transferred 3-

Age<40years 4- FSH<15 5- Sperm>10 milion counts, >3% normal morphology Exclusion Criteria: 1- Utilization of donation systems 2- Uncontrolled diseases such as Diabetes, HTN, Lupus, Renal failures,... 3- Abnormal Katyotype 4- Anatomical abnormalities(congenital, submucosal myoma, Asherman syn,...) 5- Endometriosis grade 3, 4 6- Women who had Endometrial scratch in the same cycle

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **220**

Randomization (investigator's opinion)

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

Avicenna Research Institute Ethics Committee

Street address

Avicenna Research Institute, Shahid Beheshti university, Velenjak Avenue, Chamran High way

City

Tehran

Postal code

1941913114

Approval date

2016-08-30, 1395/06/09

Ethics committee reference number

IR.ACECR.Avicenna.REC.1395.9

Health conditions studied

1

Description of health condition studied

unovulation female infertility

ICD-10 code

N97

ICD-10 code description

Female infertility associated with anovulation

2

Description of health condition studied

tubal female inferility

ICD-10 code

N97.1

ICD-10 code description

Female infertility of tubal origin

3

Description of health condition studied

male factor female infertility

ICD-10 code

N97.4

ICD-10 code description

Female infertility associated with male factors

4

Description of health condition studied

unspecified female infertility

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

5

Description of health condition studied

complication of artificial fertilization

ICD-10 code

N98.9

ICD-10 code description

Complication associated with artificial fertilization, unspecified

Primary outcomes

1

Description

ICSI Outcome(chemical pregnancy)

Timepoint

two weeks afert embryo transfer

Method of measurement

serum Beta HCG

2

Description

Clinical pregnancy

Timepoint

three weeks after embryo transfer

Method of measurement

transvaginal ultrasound

Secondary outcomes

1

Description

oocyte quality

Timepoint

on the oocyte collection day

Method of measurement

morphologic assesment with microscope

2

Description

embryo quality

Timepoint

2 or 3 days after oocyte collection

Method of measurement

morphologic assesment with microscope

3

Description

fertilization rate

Timepoint

2 or 3 days after oocyte collection

Method of measurement

(embros number/injected oocytes numbers) * 100

4

Description

prednisolone complications

Timepoint

any time of trial

Method of measurement

history and lab tests

Intervention groups

1

Description

placebo of prednisolone about 1.5 months

Category

Placebo

2

Description

prednisolone 10 mg daily about 1.5 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Avicenna Infertility Clinic

Full name of responsible person

Dr Farnaz Fatemi

Street address

No. 97, Yakhchal st., Shariati avenue,Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Avicenna Infertility Clinic

Full name of responsible person

Dr Mohammad Mehdi Akhondi

Street address

No. 97, Yakhchal st., Shariati avenue,Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Avicenna Infertility Clinic

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

Avicenna Infertility Clinic

Full name of responsible person

Dr Farnaz Fatemi

Position

MD, OB&GYN, Infertility fellowship

Other areas of specialty/work

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Name of organization / entity

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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