

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Efficacy of gonadotropin-releasing hormone agonist addition for luteal phase support in women with repeated implantation failure undergoing intracytoplasmic sperm injection cycles

Protocol summary

Summary

For support of Luteal phase routinely we use progesterone suppository or intramuscular route. GnRh agonist induces the increase of FSH and LH. There is no evidence to increase anomalies in fetus. In this trial research we are going to study the efficacy of single dose of 0.1 mg Decapeptide (6 days after ovum pick up in women undergoing antagonist protocol cycle and history of two or more IVF (In vitro Fertilization) failure in Avicenna center. After excluding anatomical and thyroidal factors and hydrosalpinx in women under 42 years, there are two groups: A) administration of cyclogest supp. 400 mg/BID after ICSI B) administration of cyclogest supp. 400 mg/BID after ICSI and 0.1 mg Decapeptide 6 days after ovum pick up subcutaneously. Implantation rate, (conception rate per embryo transfer) CPR, ongoing pregnancy rate, abortion below 10 weeks, twin pregnancy, β HCG 14 days after embryo transfer will be evaluated.

General information

Acronym

intracytoplasmic sperm injection cycles. Gonadotropin releasing hormone.

IRCT registration information

IRCT registration number: **IRCT201211111430N1**

Registration date: **2013-04-17, 1392/01/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-04-17, 1392/01/28

Registrant information

Name

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Name of organization / entity

Jahad University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Jahad of University

Expected recruitment start date

2013-04-21, 1392/02/01

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

Efficacy of gonadotropin-releasing hormone agonist addition for luteal phase support in women with repeated implantation failure undergoing intracytoplasmic sperm injection cycles

Public title

The effect of decapeptide on treatment of infertile women in ICSI (Intracytoplasmic Sperm Injection) cycles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: couples with two or more IVF Failure with good quality embryo transfer; women with antagonist cycle; women with at least one embryo for transfer; women

under IVF with one's gamet and women under 42 years.
Exclusion criteria: cycles with preimplantation genetic diagnosis; women with anatomical uterine disorders or hydrosalpinx and women with thyroid disorders.

Age

To 42 years old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 100

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

Research center of Jihad-Avicenna

Street address

Velenjak-Shahid Beheshti university-Jihad of university

City

Tehran

Postal code

19615-1177

Approval date

2012-11-20, 1391/08/30

Ethics committee reference number

91/5214

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

Pregnancy

Timepoint

Ten days, 3 weeks, 3 months and 5 months after

Method of measurement

HCG, sonography, follow up

Secondary outcomes

1

Description

abortion

Timepoint

every 3 months

Method of measurement

sonography-follow up

2

Description

Twin pregnancy

Timepoint

Vaginal ultrasonography in 6-8 weeks

Method of measurement

Number of gestational sacs

Intervention groups

1

Description

Six days after ovum pick up single dose of 0.1 mg

Decapeptide-S.C (Intervention group)

Category

Treatment - Drugs

2

Description

There is no intervention in control group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility and recurrent pregnancy loss of Avicenna

Full name of responsible person

Mohammadzadeh Afsaneh M.D

Street address

Shariati-Yakhchal

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Reaserch center of Avicenna

Full name of responsible person

Akhondi.Mohammad Mehdi.PHD

Street address

Shahid Beheshti university

City

Tehran

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

Yes

Title of funding source

Reaserch center of Avicenna

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**

Infertility and recurrent pregnancy loss center of
Avecinna

Full name of responsible person

Simin.Zafardoost

Position

Obstetrics and Gynecologist-Fellowship of infertility

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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