

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effects of GnRH agonist for luteal support on improvement of intracytoplasmic sperm injection cycles: clinical trial

Protocol summary

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Summary

This study was designed to evaluate the effectiveness of GnRh agonist for luteal support on improvement of intracytoplasmic sperm injection (ICSI) cycles. This clinical trial is performed in Infertility and IVF ward, Taleghani hospital. 240 infertile patients who candidate ICSI with normal ovarian response are recruited into the study in two groups according to randomization method. Subcutaneous injection of 0.1 mg Triptorelin or placebo is performed 6 days after ICSI. Luteal support is performed for all participants as a same protocol (Vaginal Cyclogest 400 mg twice/day). Chemical and clinical pregnancy rate and abortion rate will be analyzed.

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101729027N2**

Registration date: **2016-10-24, 1395/08/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-24, 1395/08/03

Registrant information

Name

Leila Nazari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

Scientific title

Effects of GnRH agonist for luteal support on improvement of intracytoplasmic sperm injection cycles: clinical trial

Public title

Effects of GnRH agonist for luteal support on improvement of intracytoplasmic sperm injection cycles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 20-38; Body mass index (BMI) between 20-30; fresh embryo transfer cycles; 3rd menstrual day serum FSH below 10; absence of low ovarian response according Bologna Criteria Exclusion criteria: unwillingness to continue; absence of good quality embryo; ovarian hyper stimulation (more than 18 mature follicle during ovarian stimulation)

Age

From **20 years** old to **38 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **240**

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

Ethics committee of Shahid Beheshti University of
Medical Sciences

Street address

Velenjak, Yaman St, Chamran highway

City

Tehran

Postal code

Approval date

2016-05-28, 1395/03/08

Ethics committee reference number

IR.SBMU.MSP.REC.1395.65

Health conditions studied

1

Description of health condition studied

Noninflammatory disorders of female genital tract

ICD-10 code

N98.9

ICD-10 code description

Complication associated with artificial fertilization,
unspecified

Primary outcomes

1

Description

Clinical pregnancy

Timepoint

4 weeks after embryo transfer

Method of measurement

Transvaginal ultrasound

2

Description

Chemical pregnancy

Timepoint

2 weeks after embryo transfer

Method of measurement

Serum BHCG

Secondary outcomes

1

Description

Ongoing pregnancy

Timepoint

10 weeks after embryo transfer

Method of measurement

Fetal heart beat in ultrasound

2

Description

Abortion

Timepoint

Before 20 weeks of pregnancy

Method of measurement

Fetal demise before 20 weeks of gestation

Intervention groups

1

Description

Intervention group: Subcutaneous injection of Triptorelin
(0.1 mg) 6 days after ICSI

Category

Treatment - Drugs

2

Description

Control group: Subcutaneous injection of placebo 6 days
after ICSI

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility and IVF ward of Talghani hospital

Full name of responsible person

Leila Nazari

Street address

Yaman St, Velenjak, Chamran highway

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences, Yaman st, Velenjak, Chamran highway

City

Tehran

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

Yes

Title of funding source

Vice Chancellor for research of Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Leila Nazari

Position

Assistant professor

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Contact**Name of organization / entity**

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Full name of responsible person

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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