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

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.

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

+98 21 2271 8000

Email address

nazari@sbmu.ac.ir

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

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
Other areas of specialty/work
Street address
Taleghani hospital, Yaman st, Velenjak, Chamran highway
City
Tehran
Postal code
Phone
+98 21 2243 2558
Fax
Email
nazari@sbmu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Nasrin Saharkhiz
Position
Associated professor
Other areas of specialty/work
Street address
Taleghani hospital, Yaman st, Velenjak, Chamran highway
City
Tehran
Postal code
Phone
+98 21 2243 2558
Fax
Email
saharkhiz1377@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Leila Nazari
Position
Assistant professor
Other areas of specialty/work
Street address
Taleghani hospital, Yaman st, Velenjak, Chamran highway
City
Tehran
Postal code
Phone
+98 21 2243 2558
Fax
Email
nazari@sbmu.ac.ir
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