Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of GnRH agonist for luteal support on improvement of IVF/ICSI cycles

Protocol summary

Study aim
This study was designed to evaluate the effectiveness of GnRh agonist for luteal support on improvement of intracytoplasmic sperm injection (ICSI) cycles.

Design
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 and 9 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.

Settings and conduct
This clinical trial is performed in Infertility and IVF ward, Taleghani hospital

Participants/Inclusion and exclusion criteria
Age between 20-38 years old; body mass index (BMI) between 20-30; fresh embryo transfer cycles; 3rd menstrual day serum FSH below 10; absence of low ovarian response

Intervention groups
Intervention group: subcutaneous injection of Triptorelin (0.1 mg) 6 days after ICSI. Control group: subcutaneous injection of placebo 6 days after ICSI.

Main outcome variables
Chemical pregnancy; clinical pregnancy; ongoing pregnancy; abortion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160722029027N6**
Registration date: **2018-09-20, 1397/06/29**
Registration timing: **registered_while_recruiting**
Last update: **2018-09-20, 1397/06/29**
Update count: **0**

Registration date
2018-09-20, 1397/06/29

Registrant information

Name
Leila Nazari

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 2271 8000

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nazari@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-21, 1397/01/01

Expected recruitment end date
2018-09-21, 1397/06/30

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 IVF/ICSI cycles

Public title
Effects of GnRH agonist for luteal support on improvement of IVF/ICSI cycles

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 20-38 years old 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

- Participant
- Outcome assessor

Sample size
Target sample size: **240**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling was randomized . In this method, we use the numerical random number table to choose the numbers, for example, if the sample size is two digits. First, select a two-digit number completely randomly, for example by placing the pencil tip, and then go ahead and select two-digit numbers to get the required number.

Blinding (investigator's opinion)
Double blinded

Blinding description
This is double-blind study, that the participants do not know which of the two control or test groups belong, and also the observers (researchers) do not know who the group is.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی شهید بهشتی

Street address
Velenjak, Yaman St, Chamran highway

City
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Postal code
1983969411

Approval date
2018-01-26, 1396/11/06

Ethics committee reference number
IR.SBMU.RETECH.REC.1396.994

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 and 9 days after ICSI
Category
Treatment - Drugs

2

Description
Control group: Subcutaneous injection of placebo(Normal saline) 6 and 9 days after ICS
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
IVF Infertility and IVF ward of Talghani hospital
Full name of responsible person
Leila Nazari
Street address
Yaman St., Velenjak, Chamran highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

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
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
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Position
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Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Chemical pregnancy-Clinical pregnancy-Ongoing pregnancy-Abortion

When the data will become available and for how long

Without restriction

To whom data/document is available

All researchers

Under which criteria data/document could be used

With permission from the author responsible

From where data/document is obtainable

Email to author responsible

What processes are involved for a request to access data/document

Email to author responsible

Comments