

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison administration single dose GnRH agonist(Triptrolin) with placebo in the luteal phase on clinical pregnancy rate in ART cycle in the infertile women.

Protocol summary

Summary

Randomized double blind clinical trial .single center to evaluate effect of single dose GnRH agonist(Triptrolin 0.1 mg) for luteal phase support on the probability of clinical pregnancy rates in ART cycle.328 women who were referred to Omid clinic in 2014,divided into a luteal-phase triptrolin and placebo group by means of computer generated randomization program.Patients received either GnRH agonist(long protocol)or GnRH antagonist protocol. For agonist group,daily injection of Buserlin 0.5 mg subcutaneous (sc) started on the 21st day of preceding cycle.The dose was reduced to 0.25mg/day on commencement of menstrual bleeding.Gonadotropin stimulating hormone(rFSH or HMG) started on the second day of menstrual bleeding to control ovarian stimulation, Dose ranged between 150 -450 IU.Administration of drugs continued till 3 follicles with 18 mm. Patients who received antagonist protocol,Gonadotropin stimulating hormone(rFSH or HMG) started on the second day and continued till the size of follicles became 14 mm,then GnRH antagonist(Cetrotide, 0.25mg, sc) was started and continued till three follicles reached 18mm.then 10000 IU hcg(human chorionic gonadotropin)intramuscular administered. Ovum retrieval was undertaken 36 h after hcg administered under sonographic guide with 17 gauge needle.embryo transfer(ET) was performed on day 2 or 3 after ovum retrieval.Three days after ET ,0.1 mg triptrolin was injected for patients in intervention group and normal saline injection in control group.For all cases progesterone was administered after ovum retrieval till fetus cardiac activity detected.clinical pregnancy was identified by development of a gestational sac. Secondary consequence ,was increased implantation rate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014030916912N1**
Registration date: **2014-06-26, 1393/04/05**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-26, 1393/04/05

Registrant information

Name

Saeedeh Gharahjeh

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8873 6218

Email address

s-gharahgeh@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-05-05, 1393/02/15

Expected recruitment end date

2014-08-21, 1393/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison administration single dose GNRH agonist(Triptrolin) with placebo in the luteal phase on clinical pregnancy rate in ART cycle in the infertile women.

Public title

Effect of administration GNRH agonist(Triptrolin) on clinical pregnancy in ART

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria :couples undergoing ART with their own gametes ; good and high responder women;women age less than 40,FSH level less than 10 mIU/ml on third day of mense ,AMH more than 1.1 ng/ml; couples having at least one embryo available for transfer. Exclusion criteria:couples undergoing ART with donation gamate;azospermia;poor responder women: women age more than 40 ,FSH level more than 10 mIU/ml on third day of mense,AMH less than 1.1 ng/ml and less than 4 follicles in previous ART cycle.

Age

From **16 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **328**

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

Tehran University of Medical Sciences

Street address

Ghods street,Keshavarz avenue, university central organization.sixth floor

City

Tehran

Postal code

Approval date

2014-03-12, 1392/12/21

Ethics committee reference number

92/130/2996/3

Health conditions studied

1

Description of health condition studied

INFERTILITY

ICD-10 code

N97.4

ICD-10 code description

Female infertility associated with male factors

Primary outcomes

1

Description

clinical pregnancy

Timepoint

eight week after intervention

Method of measurement

vaginal sonography

Secondary outcomes

1

Description

Implantation rate

Timepoint

Ten week after intervention

Method of measurement

vaginal sonography

Intervention groups

1

Description

Three days after embryo transfer ,0.1 mg(1ml) triptrolin subcutaneous was injected for patients in intervention group.

Category

Treatment - Drugs

2

Description

Patients in control group received 1ml normal saline subcutaneous injection three days after embryo transfer.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

shariati hospital

Full name of responsible person

saeedeh gharahjeh

Street address

Jalal al ahmad avenue

City

Tehrah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research , Tehran University of Medical Science

Full name of responsible person

Dr Akbar Fotouhi

Street address

16 Azar avenue, Keshavarz Boulevard, Tehran University of Medical Science

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 , Tehran University of Medical Science

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

Tehran University of Medical Sciences

Full name of responsible person

Saeedeh Gharahjeh

Position

Infertility fellowship

Other areas of specialty/work**Street address**

Jalal al ahmad avenue, Shariaty hospital

City

Tehran

Postal code

14114

Phone

+98 21 8490 2421

Fax

+98 21 8822 0050

Email

S-

gharahgeh@razi.ac.irDr.gharahgeh_1388@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Saeedeh Gharahjeh

Position

Infertility fellowship

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Jalal al ahmad avenue, Shariaty hospital

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Phone

+98 21 8490 2421

Fax

+98 21 8822 0050

Email

s-gharahgeh@razi.tums.ac.ir

Dr.gharahgeh_1388@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Saeedeh Gharahjeh

Position

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Jalal al ahmad avenue, Shariaty hospital

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Fax**Email**

S-

gharahgeh@razi.tums.ac.irDr.gharahgeh_1388@yahoo.com

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