Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

The effect of intrauterine administration of human chorionic gonadotropin after oocyte pick up on the outcome of intracytoplasmic sperm injection and embryo transfer (ICSI/ET) in infertile couples

Protocol summary

Summary

The aim of this study is to evaluate the effect of intrauterine injection of human chorionic gonadotropin after oocyte pick up on the outcome of intracytoplasmic sperm injection and embryo transfer (ICSI/ET) in infertile couples. Inclusion criteria are: eighteen to forty years old women candidate of intracytoplasmic sperm injection and embryo transfer (ICSI/ET); normal TSH; normal PRL; normal AMH or day 2 to 4 FSH and E2. Exclusion criteria are: Uncontrolled chronic maternal disease like endocrinopathy and autoimmune disease; endometriosis; severe hydrosalpinx; azospermia; oocyte donation; when it is required to do a surgical operation after oocyte pick up and before embryo transfer or for any reason the embryo transfer must be deferred; high risk of OHSS; morphologic embryo deficiencies. These women will be treated with the antagonist protocol for controlled ovarian stimulation and when at least 3 or more follicle with diameter of 17 mm or more is detected by transvaginal ultrasonography, the last trigger for ovulation will be induced with intramuscular injection of 10000 unit of human chorionic gonadotropin (HSG). Thirty six to 40 hours later they will be picked up their oocytes under general anesthesia. These women will have been divided randomly in two groups. The person who prepares the drug for injection will be the only person who is informed from the allocation of the patient. Immediately after oocyte pick up, the patients in the study and control groups will receive intrauterine 500 unit of HSG in up to 0.5 cc of normal saline or 0.5 cc of normal saline through intrauterine insemination (IUI) catheter with insulin syringe, respectively. Fresh embryo transfer will be take place in third or fourth day. The rate of implantation, intrauterine pregnancy, abortion, ectopic pregnancy, OHSS will be compared between the two groups.

General information

Acronym

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IRCT registration information

IRCT registration number: **IRCT201206165485N4**
Registration date: **2015-09-02, 1394/06/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-09-02, 1394/06/11

Registrant information

Name

Nazli Navali

Name of organization / entity

Tabriz University of Medical Sciences, Faculty of Medecine

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Women's Reproductive Health Research Center, Tabriz University of Medical Scienses

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-12-21, 1394/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intrauterine administration of human chorionic gonadotropin after oocyte pick up on the outcome of intracytoplasmic sperm injection and embryo transfer (ICSI/ET) in infertile couples

Public title

The effect of intrauterine administration of human chorionic gonadotropin after oocyte pick up on the outcome of intracytoplasmic sperm injection and embryo transfer (ICSI/ET) in infertile couples

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Eighteen to forty years old women candidate of intracytoplasmic sperm injection and embryo transfer (ICSI/ET); normal TSH; normal PRL; normal AMH or day 2 to 4 FSH and E2 Exclusion criteria: Uncontrolled chronic maternal disease like endocrinopathy and autoimmune disease; endometriosis; severe hydrosalpinx; azospermia; oocyte donation; when it is required to do a surgical operation after oocyte pick up and before embryo transfer or for any reason the embryo transfer must be deferred; high risk of OHSS; morphologic embryo deficiencies

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Research Deputy of Tabriz University of Medical Sciences, University of Tabriz, Golgasht street

City

Tabriz

Postal code

Approval date

2015-06-18, 1394/03/28

Ethics committee reference number

5/4/3129

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

implantation rate

Timepoint

two weeks after embryo transfer

Method of measurement

beta HCG titrating

2

Description

pregnancy rate

Timepoint

3weeks after embryo transfer

Method of measurement

ultrasonography

3

Description

heart rate detection

Timepoint

4weeks after embryo transfer

Method of measurement

ultrasonography

Secondary outcomes

1

Description

ectopic pregnancy rate, abortion rate

Timepoint

four weeks after embryo transfer

Method of measurement

beta HCG titrating, ultrasonography

2

Description

ovarian hyperstimulation rate

Timepoint

1week after transfer

Method of measurement

sign and symptoms

Intervention groups

1

Description

Intervention group 1: immediately after oocyte pick up, the patients in the study group will receive intrauterine 500 unit of human chorionic gonadotropin (HSG) with trade mark of Choriomon (IBSA) in up to 0.5 cc of normal saline through cervical canal after passing the internal os, by intrauterine insemination (IUI) catheter and insulin syringe. Then the women will rest for 10 minutes.

Category

Treatment - Drugs

2

Description

Control group: Immediately after oocyte pick up, the patients in the control group will receive 0.5 cc of normal saline through cervical canal after passing the internal os, by intrauterine insemination (IUI) catheter and insulin syringe. Then the women will rest for 10 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Nazli Navali

Street address

Artesh street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Women's Reproductive Health Research Center, Vice chancellor for research, Tabriz University of Med

Full name of responsible person

dr.Elahe Saheb Olad Madarec

Street address

Artesh street

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Women's Reproductive Health Research Center, Vice chancellor for research, Tabriz University of Med

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

Tabriz University of Medical Sciences

Full name of responsible person

Nazli Navali

Position

infertility fellowship/associate professor

Other areas of specialty/work

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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