

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Frozen Thawed Embryo Transfer Cycles: A Comparison of Pregnancy Outcomes with and without Prior Pituitary Suppression by Gonadotropin-releasing hormone Agonists

Protocol summary

Summary

1-Objectives: Our study is aimed at evaluating the pregnancy outcome rate of Frozen thawed embryo transfer (FTET) with and without GnRH agonists pretreatment. 2-Design: This experiment is designed as a randomized controlled trial in a population of southern Iranian women with documented infertility. 3-Setting and Conduct: Women with documented infertility who were candidate for FTET were studied in a one year period from November 2012 to November 2013. Study population were randomly assigned to two groups, 100 patients in each group. 4-Participants including major eligibility criteria: couples with documented infertility of any cause with the women being 20-39 years, who had frozen embryo available for transfer entered the study. 5-Intervention: In group A, patients received GnRH agonist, Busereline, to induce pituitary desensitization prior to endometrial preparation and embryo transfer. Individuals in the group B received steroid manipulation without prior downregulation of the pituitary. 6-Main outcome measures: Short term outcomes including chemical pregnancy (defined as β HCG level > 10 IU per L obtained 16 days after Frozen Thawed Embryo Transfer), clinical pregnancy (intrauterine gestational sac during ultrasound examination 5 weeks after transfer date), ongoing pregnancy rates (presence of intrauterine fetal heart motion 12 weeks after transfer date) along with implantation rate (number of gestational sacs with fetal pole detected) were measured and compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052834184N1**
Registration date: **2017-08-07, 1396/05/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-08-07, 1396/05/16

Registrant information

Name

Golnaz Namazi

Name of organization / entity

Harvard University

Country

United States

Phone

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Email address

gnamazi@partners.org

Recruitment status

Recruitment complete

Funding source

Shiraz university of medical sciences grants No 5665.

Expected recruitment start date

2012-11-01, 1391/08/11

Expected recruitment end date

2013-11-01, 1392/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Frozen Thawed Embryo Transfer Cycles: A Comparison of Pregnancy Outcomes with and without Prior Pituitary Suppression by Gonadotropin-releasing hormone

Agonists

Public title

comparison between pregnancy outcome of in vitro fertilization (assisted reproductive technology) with and without Gonadotropin-releasing hormone agonist

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: Documented infertility of any cause;Aged 20-39 years; Couples undergoing ART with their own gametes;Women stimulated with a long GnRH agonist protocol of IVF (for group A);Couples having frozen embryo available for transfer exclusion criteria: Age > 39 years; High grade endometriosis;Existence of myoma or adhesion in uterus;Body mass index (BMI) more than 29 kg/m² or less than 18 kg/m²;Oocyte donation cycles

Age

From **20 years** old to **39 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand ST,

City

Shiraz

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

5665

Health conditions studied

1

Description of health condition studied

in vitro fertilization

ICD-10 code

Z31.2

ICD-10 code description

Admission for harvesting or implantation of ova

2

Description of health condition studied

infertility

ICD-10 code

N97

ICD-10 code description

inability to achieve a pregnancy

Primary outcomes

1

Description

pregnancy outcome

Timepoint

since 16 days post transfer until delivery

Method of measurement

beta hCG, Ultrasound

Secondary outcomes

1

Description

clinical pregnancy

Timepoint

5 weeks after transfer date.

Method of measurement

observation of intrauterine gestational sac during ultrasound examination 5 weeks after transfer date.

2

Description

chemical pregnancy

Timepoint

16 days following thawed embryo transfer

Method of measurement

Serum β HCG level > 10 IU per L

3

Description

Ongoing pregnancy

Timepoint

12 weeks after transfer date

Method of measurement

presence of intrauterine fetal heart motion

4

Description

implantation rate

Timepoint

9 weeks post transfer

Method of measurement

number of gestational sacs with fetal pole detected using vaginal ultrasound to the number of transferred embryos

5

Description

Miscarriage rate

Timepoint

under the 20th week of gestation

Method of measurement

ultrasound and beta hCG

Intervention groups

1

Description

Participanpatients in group A received GnRH agonist prior to ovulation induction.0.5 mg of Busereline acetate (a GnRH agonist) (Suprefact, Hoechst AG, Germany) was injected subcutaneously daily starting on the 21st day of menstrual cycle (mid luteal phase). On the first day of menstruation, GnRH agonist dose was reduced to 0.3 mg SC per day.

Category

Treatment - Drugs

2

Description

patients in group B had steroid manipulation and routine IVF regimen without prior down-regulation of the pituitary

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz ghadir Mother and child subspecialized hospital

Full name of responsible person

Zohre Chitsazi

Street address

Mother and Child Hospital Ghadir, above gate Quran, First Town Gulshan

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Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor of research Shiraz University of Medical Sciences

Full name of responsible person

Dr. Basir Hashemi

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City

Shiraz

Grant name

Grant code / Reference number

۵۶۶۵

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

Yes

Title of funding source

vice chancellor of research Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Zohre Chitsazi

Position

Obstetrics and Gynecology resident, Doctor of medicine

Other areas of specialty/work

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Position

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Other areas of specialty/work**Street 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*