Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of Fresh and Frozen Embryo Transfer in GnRH Agonist Triggered patients: A Multicenter Study

Protocol summary

Study aim

Compare the reproductive outcomes of fresh vs frozen embryo transfer in high responder IVF patients triggered with GnRHa

Design

Women at risk for OHSS who were stimulated with GnRH antagonist protocol and triggered with GnRHa for oocyte triggering were randomly divided into two groups of either fresh embryo transfer or frozen embryo transfer on the day of oocyte triggering. In this not-blinded, phase 2 clinical trial without control group, randomization was performed using random number table.

Settings and conduct

In this multicenter, randomized clinical trial, infertile women at risk of OHSS were recruited at three fertility clinics in Iran; Yazd Research and Clinical Center for Infertility, Yazd Madar Hospital, Mashhad Novin Fertility and Infertility Center. Women were randomized into two groups. Pregnancy outcome were assessed in FET and fresh embryo transfer groups.

Participants/Inclusion and exclusion criteria

Patients with OHSS risk at the age between 20-40 yr and having a number of 14-25 follicles ≥12 mm on the day of trigger and a body mass index >18 and <35 kg/m2 without a previous history of OHSS development.

Intervention groups

Group 1: Women were stimulated with GnRH antagonist protocol and triggered with GnRHa for oocyte triggering with fresh embryo transfer Group 2: Women were stimulated with GnRH antagonist protocol and triggered with GnRHa for oocyte triggering with frozen embryo transfer

Main outcome variables

The primary outcome parameter was clinical pregnancy and the secondary outcome parameters were chemical pregnancy; live birth; OHSS development; and perinatal outcomes.

General information

Reason for update

Updating the trial regarding actual sample size, actual recruitment start and end dates

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092224512N4**
Registration date: **2016-10-03, 1395/07/12**
Registration timing: **retrospective**

Last update: **2021-03-24, 1400/01/04**
Update count: **1**

Registration date

2016-10-03, 1395/07/12

Registrant information

Name

Abbas Aflatoonian

Name of organization / entity

Yazd research and clinical center for infertility

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Deputy, Shahid Sadoughi Univesity of Medical Science

Expected recruitment start date

2014-01-01, 1392/10/11

Expected recruitment end date

2015-12-30, 1394/10/09

Actual recruitment start date

2014-01-01, 1392/10/11

Actual recruitment end date

2015-12-30, 1394/10/09

Trial completion date

2017-01-30, 1395/11/11

Scientific title

Comparison of Fresh and Frozen Embryo Transfer in GnRH Agonist Triggered patients: A Multicenter Study

Public title

Pregnancy outcome in Fresh versus Freeze embryo transfer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20-40 Hyper responded patients Detection of 14-25 follicles ≥ 12 mm on day of trigger BMI >18 and <35 kg/m2

Exclusion criteria:

Patients with <14 follicles and > 25 ≥ 12 mm on day of trigge Previous OHSS Endocrine disorders

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **1280**

Actual sample size reached: **280**

Randomization (investigator's opinion)

Randomized

Randomization description

In this multicenter, randomized clinical trial, 280 infertile women at risk of OHSS were enrolled in the study. All patients were informed about the research design and signed a written consent form. All women were randomly divided into two groups. Randomization was simple, individual using a random number table.

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

Research and Clinical center for Infertility, Shahid Sadoughi University of medical Sciences

Street address

Bouali Ave, Safayieh

City

Yazd

Province

Yazd

Postal code

8916877391

Approval date

2013-12-09, 1392/09/18

Ethics committee reference number

IRCT2016092224512N4

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

inability to achieve a pregnancy sterility, female NOS

Primary outcomes

1

Description

Clinical pregnancy rate

Timepoint

7 weeks after embryo transfer

Method of measurement

Fetal heart rate in ultra sonography

Secondary outcomes

1

Description

Chemical pregnancy rate

Timepoint

14 days after embryo transfer

Method of measurement

Beta-hCG using lab kit

2

Description

livebirth

Timepoint

36 weeks after embryo transfer

Method of measurement

A live-born baby

3

Description

Ovarian hyperstimulation syndrome

Timepoint

During ovarian stimulation

Method of measurement

Measurement of serum anti mullerian hormone level and antral follicle count

4

Description
Perinatal outcome
Timepoint
After live birth
Method of measurement
weight measurement, prematurity status

Intervention groups

1

Description
Intervention group 1: Freeze of all embryos according to embryo freezing standard protocol at the same cycle. Thaw all the embryos according to embryo thawing standard protocol and embryo transfer at the next cycle
Category
Treatment - Other

2

Description
Intervention group 2: Transfer of 2 fresh embryos at the same cycle Luteal phase support using oral Estradiol Valerat at the dose of 4 mg per day and progesterone (Cyclogest 400 mg) twice daily until observation of fetal heart activity
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Research and Clinical center for Infertility, Shahid Sadoughi University of medical Sciences
Full name of responsible person
Nasim Tabibnejad
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Recruitment center
Name of recruitment center
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Recruitment center
Name of recruitment center
Novin Infertility Center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Deputy, Shahid Sadoughi University of Medical Sciences
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Amirhooshang Mehrparvar
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dvc.research@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Deputy, Shahid Sadoughi 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

Research and Clinical center for Infertility, Shahid Sadoughi University of medical Sciences

Full name of responsible person

Nasim Tabibnejad

Position

PhD student

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

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Latest degree

Specialist

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Person responsible for updating data

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All participant data sets are to be shared

When the data will become available and for how long

2 months after the result publication

To whom data/document is available

A journal in which the results are published

Under which criteria data/document could be used

Submission of an official application via the agent that is legally in charge

From where data/document is obtainable

Yazd Reproductive Sciences Institute, Bouali Ave, Yazd, Iran. 983538247085 abbas_aflatoonian@yahoo.com

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

2 months after application

Comments