Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of GnRH-a in endometrial preparation for frozen-thawed embryo transfer cycles in patient with repeated implantation failure.

Protocol summary

Study aim

This study was conducted to investigate the effects of GnRH agonist administration on the implantation rate in the FET cycles of women with RIF, prior to estrogen-progesterone preparation of the endometrium.

Design

The case group (n = 34) received 0.1 mg/day of the GnRH agonist (Variopeptyl, VarianDarou, Iran), subcutaneous, from day 21 of the cycle preceding the actual FET cycle. On the second day of the cycle, the dose of GnRH agonist was reduced to 0.05 mg and 6 mg/day oral estradiol valerate (2 mg, Aburaihan Co., Tehran, Iran) was also started. When the endometrial thickness reached to 7.5 mm, vaginal supplementation of Cyclogest® pessaries (Cox Pharmaceuticals, Barnstaple, UK) at 400 mg twice daily was started and the GnRH agonist was also stopped. The control group (n = 33), received 6 mg/day oral estradiol valerate (2 mg, Aburaihan Co., Tehran, Iran) from the second day of the cycle without the GnRH agonist. In the two groups, frozen-thawed embryos were transferred on the fourth day of progesterone treatment.

Settings and conduct

In this randomized clinical trial, 67 infertile women with history of idiopathic RIF (at least two implantation failures), undergoing FET cycles in Yazd Reproductive Sciences Institute.

Participants/Inclusion and exclusion criteria

67 infertile women with history of idiopathic RIF (at least two implantation failures), undergoing FETcycles included. All women with endometrial polyp, uterine myoma, and uterine anomaly were excluded from the study

Intervention groups

67 infertile women with history of idiopathic RIF (at least two implantation failures), undergoing FETcycles included.

Main outcome variables

The clinical outcomes) including chemical and clinical pregnancy, in addition to implantation rates, were compared between the two groups.

General information

Reason for update

Update clinical trial based on the latest changes in method and recruitment and trial completion dates

Acronym

IRCT registration information

IRCT registration number: **IRCT201708292604N3**
Registration date: **2017-09-18, 1396/06/27**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-19, 1400/01/30**
Update count: **1**

Registration date

2017-09-18, 1396/06/27

Registrant information

Name
Robab Davar
Name of organization / entity
Yazd Research and Clinical Center for Infertility
Country
Iran (Islamic Republic of)
Phone
+98 35 1824 7085
Email address
davar@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Shahid Sadoughi Universit,y of Medical Sciences, Yazd,Iran

Expected recruitment start date

2017-08-16, 1396/05/25

Expected recruitment end date

2017-11-16, 1396/08/25

Actual recruitment start date

2017-08-01, 1396/05/10

Actual recruitment end date

2017-11-30, 1396/09/09

Trial completion date

2018-01-30, 1396/11/10

Scientific title

Effect of GnRH-a in endometrial preparation for frozen-thawed embryo transfer cycles in patient with repeated implantation failure.

Public title

Effect of GnRH-a in endometrial preparation for frozen-thawed embryo transfer cycles in patient with repeated implantation failure.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

infertile women with at least 2 previous failed implantation.

Exclusion criteria:

Endometrial polyp myoma uterine anomaly

Age

From **18 years** old to **42 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **67**

Actual sample size reached: **67**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups of 34 patients according to permutation block method of control and intervention. Therapeutic tasks within the blocks are determined in such a way that they are random, but the desired allocation ratio is achieved in each block. There are 8 blocks in each,is 8 numbers in order to reaches sample size to 64 and one block of 4 is considered. Generate random codes using random block allocation method which will be generated with the help of Random allocation software version 1. The first person eligible to enter the study is given number one and so on until the last person eligible for number 67 is given.Using a table generated by random allocation software by number, individuals are placed in the control and intervention group. The output of Random allocation software version 1 is specified as A and B in the specified blocks, which describe the number of blocks and the number of patients in each block.

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

Ethics Committee of Yazd Reproductive Sciences institute shahid sadoughi university

Street address

Yazd Reproductive Sciences Institute

City

Yazd

Province

Yazd

Postal code

8916877391

Approval date

2017-05-21, 1396/02/31

Ethics committee reference number

IR.SSU.RSI.REC.1396.1

Health conditions studied

1

Description of health condition studied

repeated implantation failure

ICD-10 code

N98.9

ICD-10 code description

complication associated with artificial fertilization ,unspecified

Primary outcomes

1

Description

chemical pregnancy

Timepoint

2 weeks after embryo transfer

Method of measurement

serum BHCG

2

Description

clinical pregnancy

Timepoint

2 wk after positive β hCG

Method of measurement

the detection of a fetal heartbeat in sonography

3

Description
Implantation rate
Timepoint
2 wk after positive β hCG
Method of measurement
the number of gestational sacs per embryos transferred

Secondary outcomes

empty

Intervention groups

1

Description
In case group , patients receive daily subcutaneous injections of 0.1 mg of GnRH-a(diphereline) starting from day 21 of previous cycles.The dose is reduce to 0.05 mg from the second day of cycle when daily oral estradiol valerate 6mg is also started.Daily vaginal progesterone 400mg twice daily is started when endometrial thickness is > 7.5 mm and GnRH_a is also stopped.
Category
Treatment - Drugs

2

Description
In control group oral estradiol 6mg daily is started from day 2 cycle without diphereline. Daily vaginal progesterone 400mg twice daily is started when endometrial thickness is > 7.5 mm
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd Reproductive Sciences Institute
Full name of responsible person
Dr.Robab Davar
Street address
Yazd Safaeye Bouali Ave.
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 7085
Email
r_davar@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd Reproductive Sciences Institute, Shahid Sadoughi University
Full name of responsible person
Dr.Robab Davar
Street address
Yazd Reproductive Sciences Institute,Bouali Ave. Safaeiyeh,Yazd
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 7085
Email
r_davar@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd Reproductive Sciences Institute, Shahid Sadoughi University
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
Yazd Reproductive Sciences Institute
Full name of responsible person
Dr.Robab Davar
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Yazd Reproductive Sciences Institute,Bouali Ave. Safaeiye
City
Yazd
Province
Yazd
Postal code
8916877391

Phone
+98 35 3824 7085
Fax
+98 35 3824 7087
Email
r_davar@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yazd Reproductive Sciences Institute
Full name of responsible person
Dr.Robab Davar
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Yazd Reproductive Sciences Institute,Bouali ave. safaeiye
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 7085
Fax
Email
r_davar@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Yazd Reproductive Sciences Institute
Full name of responsible person
Dr.Saeideh Dashti
Position
Gynecologist
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Yazd Reproductive Sciences Institute,Bouali Ave.Yazd Safaeiyeh,Yazd,Bouali Ave. Safaeiyeh,Yazd
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 7085
Fax
Email
Saeideh_dashti@yahoo.com
Web page address

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
participant data set able to be shared
When the data will become available and for how long
2 months after publication
To whom data/document is available
Journal that published the results
Under which criteria data/document could be used
A person/office that is legally in charge
From where data/document is obtainable
Yazd Reproductive Sciences Institute 983538247085 saeideh_dashti@yahoo.com
What processes are involved for a request to access data/document
Submission of legal order
Comments