Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of endometrial injury on pregnancy rate in frozen- thawed embryo transfer

Protocol summary

Study aim
Whether endometrial injury in luteal phase prior to FET cycle would improve pregnancy outcomes

Design
Women who were candidate for FET were randomly divided into two groups of either endometrial injury before embryo transfer or no endometrial injury embryo transfer. In this not-blinded, phase 2 clinical trial with control group, randomization was performed using random number table.

Settings and conduct
100 women who were candidate for FET at Yazd Research and Clinical Center for Infertility were divided randomly without blindness into two groups of either endometrial injury before embryo transfer or no endometrial injury embryo transfer.

Participants/Inclusion and exclusion criteria
The inclusion criteria include: women indicated for FET treatment, had one or more frozen embryo(s) and had a normal uterine cavity (confirmed by vaginal ultrasonography). The exclusion criteria were women <40 yrs, history of endocrine disorders (hypothyroidism, diabetes mellitus), intrauterine abnormality (uterine polyp, sub-mucosal fibroma, intrauterine adhesion) and severe endometriosis diagnosed by laparoscopy or endometrioma in ultrasound scanning.

Intervention groups
Intervention group: endometrial injury before embryo transfer Control group: No endometrial injury before embryo transfer

Main outcome variables
Chemical pregnancy

General information

Reason for update
Updating the trial according to the last changes in inclusion and exclusion criteria, actual number of cases, date of recruitment and trial completion

Acronym

IRCT registration information
IRCT registration number: **IRCT2015101324512N1**
Registration date: **2015-11-13, 1394/08/22**
Registration timing: **retrospective**

Last update: **2022-01-12, 1400/10/22**
Update count: **2**

Registration date
2015-11-13, 1394/08/22

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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+98 358247085

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Recruitment status
Recruitment complete

Funding source
Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences

Expected recruitment start date
2015-03-01, 1393/12/10

Expected recruitment end date
2015-06-30, 1394/04/09

Actual recruitment start date
2015-03-01, 1393/12/10

Actual recruitment end date
2015-06-30, 1394/04/09

Trial completion date
2015-12-29, 1394/10/08

Scientific title

The effect of endometrial injury on pregnancy rate in frozen- thawed embryo transfer

Public title
The effect of endometrial injury on pregnancy rate in frozen- thawed embryo transfer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infertile patients candidate for frozen- thawed embryo transfer who had one or more frozen embryo(s) Women with a normal uterine cavity (confirmed by vaginal ultrasonography).
Exclusion criteria:
Women >40 yrs History of endocrine disorders (hypothyroidism, diabetes mellitus) Intrauterine abnormality (uterine polyp, sub-mucosal fibroma, intrauterine adhesion) Severe endometriosis diagnosed by laparoscopy or endometrioma in ultrasound scanning.
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **120**
Actual sample size reached: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
In this trial, 100 infertile women who were candidate for frozen embryo transfer 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
Shahid Sadoughi University of Medical Sciences
Street address
Yazd, Bouali Ave, Safayeh، Research and Clinical Center for Infertility
City
yazd
Province
Yazd
Postal code
8916877391
Approval date
2015-02-10, 1393/11/21
Ethics committee reference number
445

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
N98.9
ICD-10 code description
Complication associated with artificial fertilization, unspecified

Primary outcomes

1

Description
Chemicall pregnancy
Timepoint
14 days after transfer
Method of measurement
B-HCG test

Secondary outcomes

1

Description
Clinical pregnancy
Timepoint
3 weeks after positive B-HCG
Method of measurement
vaginal ultrasonography

Intervention groups

1

Description
In intervention group (50 patients)in cycle 21-23 days (before embryo transfer cycle) ,the edometrium is scratched with piple .
Category
Treatment - Drugs

2

Description
No intervention in control group is done.

Category
Treatment - Drugs

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
Dr.Abass Aflatounian, Professor of Shahid Sadoughi University of medical sciences
Street address
Yazd, Bouali Ave, Safayeh، Research and Clinical Center for Infertility
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abbas_aflatooian@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research and technology, Yazd Shahid Sadoughi Medical Sciences
Full name of responsible person
Masoud Mirzaei
Street address
Bahonar Square
City
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Postal code
8916978477
Phone
+98 35 3724 0171
Email
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
Deputy of Research and technology, Yazd Shahid Sadoughi 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
Dr.Abass Aflatounian
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Position

Professor

Latest degree

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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

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

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

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

Comments