

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 358247085

Email address

abbas-aflatoonian@ssu.ac.ir

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

Chemical 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 endometrium 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**City**

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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

Yazd

Province

Yazd

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8916978477

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+98 35 3724 0171

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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 sourceDeputy 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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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**Research and Clinical Center for Infertility, Shahid
Sadoughi University of Medical Sciences**Full name of responsible person**

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Email

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