

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effect local endometrial injury on implantation and pregnancy rate in follicular versus luteal phases of the menstrual cycle in patients undergoing frozen embryo transfer with a history of at least one IVF failure

Protocol summary

Study aim

The main objective of this study is to compare the efficacy of local endometrial injury (LEI) in follicular phase versus luteal phase on pregnancy rate in (frozen embryo transfer) FET cycle in women referred to Infertility Clinic of Arash Women's Hospital with a history of at least one failure in IVF.

Design

This study is designed as a clinical trial with a parallel random allocation and a 1: 1 ratio.

Settings and conduct

This clinical trial will be conducted at Arash Women's Hospital on infertile women undergoing FET. Participants will randomly be divided into two groups of 68. Local Endometrial injury (LEI) process will be performed in the follicular phase for group 1, and it will be performed in the luteal phase in group 2. The LEI process will be performed with scratching endometrium by using an endometrial pipelle instrument. After 14 days, If the Triple line endometrium pattern is seen or endometrial thickness is above 7 mm, progesterone will be started as a Cyclogest suppository. After at least 3 to 4 days, two or three frozen embryos (two to three days old) will be transferred. serum β HCG level will be checked after 2 weeks. If the β hcg level rises more than 15 iu/L, a TVS will be performed within 5 weeks later for assessment of gestational Sac (GS). In the presence of GS, pregnant women will be followed up until 12 weeks of pregnancy.

Participants/Inclusion and exclusion criteria

Participants should: be aged under 40 years old; have normal body mass index; have a normal uterine cavity; have not used OCP or GnRH; have not to had endometrial hyperplasia or malignancy, active vaginal and cervical infections, and systemic disease.

Intervention groups

Group 1: local endometrial injury in the follicular phase

Group 2: local endometrial injury in the luteal phase

Main outcome variables

Implantation and chemical pregnancy rates

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110731007165N4**

Registration date: **2018-08-31, 1397/06/09**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-31, 1397/06/09**

Update count: **0**

Registration date

2018-08-31, 1397/06/09

Registrant information

Name

Ladan Kashani

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8828 1866

Email address

kashani_ladan@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect local endometrial injury on implantation and pregnancy rate in follicular versus luteal phases of the menstrual cycle in patients undergoing frozen embryo transfer with a history of at least one IVF failure

Public title

Comparison of local endometrial injury efficacy in follicular versus luteal phases on the success rate of frozen embryo transfer cycle

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Aged under 40 years old Hysterosalpingography (HSG) or hysteroscopy showed a normal uterine cavity Body Mass Index < 30 Have a history of one or more IVF failures Women who were not using Oral Contraceptives (OCP) or GnRH in previous ART cycle Have indication for LEI (Local Endometrial injury) Patients who had given their written, informed consent for participation

Exclusion criteria:

Intrauterine abnormalities shown in sonography or imaging such as myoma, Ascherman syndrome, etc ...), endometrial hyperplasia and cancer Active vaginal and cervical infections Systemic disease (systemic lupus eritematoso, Diabetes, Hypertension, etc ...)

Age

To 40 years old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 136

Randomization (investigator's opinion)

Randomized

Randomization description

Our considered sample size is 136 (with 68 people in each group). Block randomization method will be designed by using online randomization list provided by <https://www.sealedenvelope.com>

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 Tehran University of Medical Sciences

Street address

Qods St, Keshavarz Blvd, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2017-07-22, 1396/04/31

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1396.2911

Health conditions studied**1****Description of health condition studied**

Female infertility

ICD-10 code

N97

ICD-10 code description

inability to achieve a pregnancy sterility, female NOS

Primary outcomes**1****Description**

Chemical Pregnancy Rate

Timepoint

2 weeks after FET

Method of measurement

Pregnancy test (BHCG)

2**Description**

Implantation Rate

Timepoint

5 weeks after positive BHCG Test

Method of measurement

Trans Vaginal Sono

Secondary outcomes**1****Description**

Ongoing Pregnancy Rate

Timepoint

upto 12 weeks of gestation

Method of measurement

Diagnosis of gynecologist

Intervention groups**1****Description**

in group 1: Making endometrial injury by pipelle instrument in the follicular phase (at days 4-6 and before FET).The LEI process will be performed with scratching endometrium by using an endometrial pipelle instrument. After 14 days, If the Triple line endometrium pattern is seen or endometrial thickness is above 7 mm, progesterone will be started as a Cyclogest suppository. After at least 3 to 4 days, two or three frozen embryos (two to three days old) will be transferred. `

Category

Treatment - Other

2**Description**

in group 2: Making endometrial injury by pipelle instrument in the luteal phase (at days 21-23 and before FET). The LEI process will be performed with scratching endometrium by using an endometrial pipelle instrument. After 14 days, If the Triple line endometrium pattern is seen or endometrial thickness is above 7 mm, progesterone will be started as a Cyclogest suppository. After at least 3 to 4 days, two or three frozen embryos (two to three days old) will be transferred. `

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Arash women's hospital

Full name of responsible person

Dr.ladan Kashani

Street address

No. 162 Alley (Abdul Majid), Shahid Baghdarnia Street (North Rashid), Shahid Bagheri Highway, Resalat Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

+98 21 7788 3283

Email

Kashani_ladan@tums.ac.ir

Web page address<http://arash.tums.ac.ir/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Ali Sahraian

Street address

Qods St, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3619

Fax

+98 21 8163 3611

Email

rmo@tums.ac.ir

Web page address<http://vcr.tums.ac.ir/>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Arash Women 's Hospital

Full name of responsible person

Dr.Zahra Parsaeian

Position

OB/GYN RESIDENT

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No. 162 Alley (Abdul Majid), Shahid Baghdarnia Street (North Rashid), Shahid Bagheri Highway, Resalat Highway, Tehran, Iran

City

Tehran
Province
Tehran
Postal code
1653915981
Phone
+98 21 7771 9922
Fax
+98 21 7788 3196
Email
zparsaiyan6@gmail.com
Web page address
<http://arash.tums.ac.ir/>

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr.Ladan Kashani
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
No. 162 Alley (Abdul Majid), Shahid Baghdarnia Street
(North Rashid), Shahid Bagheri Highway, Resalat
Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1653915981
Phone
+98 21 7771 9922
Fax
+98 21 7788 3196
Email
Kashani_ladan@tums.ac.ir
Web page address
<http://arash.tums.ac.ir/>

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ladan Kashani
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
No. 162 Alley (Abdul Majid), Shahid Baghdarnia Street
(North Rashid), Shahid Bagheri Highway, Resalat
Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1653915981
Phone
+98 21 7788 3195
Fax
Email
Kashani_ladan@tums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available