

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The effect of pretreatment with vaginal microbial supplement on the outcomes of freeze-embryo transfer cycles in infertile women

Protocol summary

Study aim

Vaginal microbial supplement on FET cycles

Design

Randomized clinical trial

Settings and conduct

This study is a clinical trial. Participants will be selected from infertile patients under the age of 40 who are referred to the Yas Infertility Center who are candidates for embryo transfer. Patients with genetic disease diagnosed in their own or spouse, people with a specific systemic or chronic disease (diabetes, hypertension, endocrine problems, autoimmune diseases, endometriosis, etc.) are excluded. All embryos have been frozen in quality a and b. On this basis, 90 patients were enrolled in the study and randomly divided into two groups of experimental and control groups. Two weeks before the start of the cycle, patients undergo vaginal examination. In the event of any vaginal infection, they were excluded. Then, in the experimental group, the vaginal microbial suppository (lactate) as a nocturnal administered for one week. Then, on the second day of menses, they will refer to endometrial preparations. In the control group, patients do not receive microbial supplements, and on the second day they refer to the uterus for freeze transfer. The process of endometrial preparation is according to the current protocol. According to the age of the patient, 1 to 3 fetuses a and b are transmitted to the uterus on the fifth day. In case of severe and severe transfusion, or return of the fetus to the catheter, the patient is excluded from the study. After that, the outcome of pregnancy will be compared to the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All candidate for FET cycle, embryo grade A or B Exclusion criteria: Genetic dis., diabetes, hypertension, endometriosis, autoimmune dis.

Intervention groups

All the patients who are candidate for frozen embryo transfer

Main outcome variables

Chemical ,clinical pregnancy rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091012002576N17**

Registration date: **2019-04-06, 1398/01/17**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-06, 1398/01/17**

Update count: **0**

Registration date

2019-04-06, 1398/01/17

Registrant information

Name

Fatemeh Davari Tanha

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of pretreatment with vaginal microbial supplement on the outcomes of freeze-embryo transfer cycles in infertile women

Public title
The effect of pretreatment with vaginal microbial supplement on the outcomes of freeze-embryo transfer cycles in infertile women

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having freeze embryos from the previous IVF cycle Age 20 to 40 years old lack of anatomical lesions in the uterus absence of vaginitis and cervicitis
Exclusion criteria:
Patients with known genetic disease on their own or spouse People with certain systemic or chronic diseases (diabetes, hypertension, endocrine problems, autoimmune diseases, endometriosis, etc.) Embryos that frozen more than 5 years. Embryos with poor quality after thowing Vaginal infection or cervicitis

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

Gender
Female

Phase
4

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Random Number Tables

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients are included according to the table of random numbers. In the patient group, the lactobacterial suppository is taken daily two weeks before the start of the study. The control group does not use any drug before endometrial preparation. Subsequently, both groups are included in the standard regime for frozen embryo transfer. in both groups embryo transfer performs by embryologist in blind, then 14 days later, the result of the pregnancy test is reported.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of the Tehran University of Medical Sciences

Street address

Yas hospital, North Ostadnejatollahi, Karimkhan Bridge, Villa street

City

Tehran

Province

Tehran

Postal code

1597856511

Approval date

2018-12-30, 1397/10/09

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.657

Health conditions studied

1

Description of health condition studied

Recurrent IVF failure

ICD-10 code

E00-E90

ICD-10 code description

Recurrent IVF failure

Primary outcomes

1

Description

embryo implantation

Timepoint

2 weeks

Method of measurement

B HCG titrage

Secondary outcomes

1

Description

Checking gestational sac in ultrasound

Timepoint

4 weeks

Method of measurement

ultrasound

Intervention groups

1

Description

Intervention group: forty five patients include in the case group and received lactatovage suppository two weeks before embryo transfer.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

the infertility center at Yas hospital

Full name of responsible person

Dr Fatemeh Davari tanha

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North Ostad Nejatollahi- Villa street, Karimkhan Bridge

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Miss Atefeh Ahmadi خانم عاطفه احمدی

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Deputy research of TUMS; Fifth floor of Central building of Tehran University of Medical Sciences, Ghodse Avenue, Keshavarz Boulevard

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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

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Davari Tanha

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

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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 data anonymously are available

When the data will become available and for how long

After completing study at 2020 and for one year

To whom data/document is available

All medical researchers

Under which criteria data/document could be used

After confirmation of author, every analysis is permitted

From where data/document is obtainable

Deputy research of Tehran University of Medical Sciences

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

Asking from research employee at deputy of research in TUMS

Comments