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 excludedl. Then, in the experimental group, the vaginal microbial suppository (lactate) as a nocturnal adminstrated for one week. Then, on the second day of mens, 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 orB 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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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 Boulvard
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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

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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