Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

The effect of vaginal probiotic capsule on fertility in women with recurrent implantation failure: Clinical Trial

Protocol summary

Study aim

Determining the effect of using vaginal probiotic capsules on fertility in women with recurrent implantation failure (RIF)

Design

Written and informed consent will be obtained from people with RIF who are our target population in this project (200 people in each group). This product will be used vaginally three months before embryo transfer twice a day.

Settings and conduct

The study will be conducted in Valiasr International Hospital, Tabriz. Study subjects will receive probiotic pills according to the protocol. Pregnancy and clinical pregnancy rate will be evaluated. Finally, the number of babies born to affected individuals will be evaluated and compared with the control group that did not receive any treatment.

Participants/Inclusion and exclusion criteria

Patients from East Azerbaijan Having at least three implantation failures after IVF/ICSI Having primary infertility The thickness of the endometrium on the day of ovulation induction with HCG should be less than 6 mm Having regular menstrual cycles BMI under 30 Do not have any type of immunotherapy in their medical history.

Intervention groups

Subjects will receive probiotic tablets (Provage vaginal probiotic capsule (Gostaresh Milad Pharmed Co)) according to the protocol. The ingredients (per one capsule (500 mg)) include Lactobacillus Gasseri 1*0.5 Billion CFU < Lactobacillus Rhamnosus 1*0.5 Billion CFU < Maltodextrin 100 mg. This product will be used three months before embryo transfer twice a day to restore and maintain the health of the vaginal flora by improving its pH level.

Main outcome variables

1- Pregnancy rate by serum β-hCG protein measurement and based on the gestational sac view and ultrasound at 6 or 7 weeks of pregnancy. 2- The number of babies born by the affected patients in compared with the control group that received no treatment.

General information

Reason for update

Acronym

RIF

IRCT registration information

IRCT registration number: **IRCT20160422027520N21**
Registration date: **2023-01-24, 1401/11/04**
Registration timing: **prospective**

Last update: **2023-01-24, 1401/11/04**
Update count: **0**

Registration date

2023-01-24, 1401/11/04

Registrant information

Name

Mehdi Yousefi

Name of organization / entity

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Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-19, 1401/11/30

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of vaginal probiotic capsule on fertility in women with recurrent implantation failure: Clinical Trial

Public title
The effect of vaginal probiotic capsule on fertility in women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients from East Azerbaijan Having at least three implantation failures after IVF/ICSI Having primary infertility The thickness of the endometrium on the day of ovulation induction with HCG should be less than 6 mm Having regular menstrual cycles BMI under 30 Do not have any type of immunotherapy in their medical history.
Exclusion criteria:
Patients under 18 years old and over 41 years old Having polycystic ovarian syndrome Poor ovarian reserve Having chromosomal abnormalities Positive HIV, HCV or HBV tests Patients with intrauterine anomalies. Patients with coagulation problems.
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
2
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
At first, the sample size of 200 patients with RIF that met our inclusion criteria was considered as the total sample size. 'Random allocation rule' method was used for randomization, where numbers were randomly assigned to cards on a random order of one to 200. Even numbers were assigned to the treatment group and odd numbers to the control group (who did not receive any treatment). In this method, the balance will be reached at the end of the study in the number of people assigned to each group. Each card was placed in sealed and opaque envelopes to hide the random assignment.
Blinding (investigator's opinion)
Double blinded
Blinding description
The participants and the person who analyzed the results were blinded in this study. Participants were aware of the study before being randomized and informed consent was obtained from them. It should be noted that the person analyzing the results had no other role in this study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences , Daneshghah st, Tabriz,
City
Tabriz
Province
East Azarbaijan
Postal code
6446-14155
Approval date
2022-12-05, 1401/09/14
Ethics committee reference number
IR.TBZMED.REC.1401.799

Health conditions studied

1

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

Primary outcomes

1

Description
Pregnancy rate
Timepoint
After positive beta-hCG test, clinical pregnancy was evaluated at 5-6 week
Method of measurement
Examining the formation of gestational sac using Sonography method

2

Description
Live birth rate
Timepoint
9 months
Method of measurement
People with positive β-hCG test after treatment will be continuously monitored with the help of gynecologists. After about 9 months, we will evaluate the number of babies born.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Vaginal probiotic capsule (Three months before embryo transfer, two tablets a day vaginally). Provage vaginal probiotic capsule (Gostaresh Milad Pharmed Co) The ingredients (per one capsule (500 mg)) include Lactobacillus Gasseri 1*0.5 Billion CFU < Lactobacillus Rhamnosus 1*0.5 Billion CFU < Maltodextrin 100 mg.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility center at Valiasr Hospital
Full name of responsible person
Dr. Mehdi Yousefi
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Infertility center at Valiasr Hospital, Aflak-nama Sq, Zaferaniyeh Ave, Tabriz
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Sponsors / Funding sources

1

Sponsor
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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
Tabriz 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
Tabriz University of Medical Sciences
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Mehdi Yousefi
Position
PhD in Medical Immunology, Associate Professor
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Immunology
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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