

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

The effect of probiotic treatment in infertile women who underwent intrauterine insemination in Yas hospital

Protocol summary

Study aim

An interventional study that is designed to evaluate the effect of probiotic treatment in intrauterine insemination

Design

Phase 3 clinical trial with a control group, parallel design, using the random allocation rule is performed on 194 patients.

Settings and conduct

This randomized study will be performed on 194 infertile women who refer to Yas Hospital, using a convenient sampling method. This study is performed single-blind, the gynecologist who does intrauterine insemination does not know the patient group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Infertile women older than 18 years, candidate for intrauterine insemination with a History of at least twice failure in intrauterine insemination.
Exclusion criteria: Bacterial vaginitis, withdrawal to participate in the study.

Intervention groups

In the intervention group, lactatovage suppository will be prescribed once per night two weeks before intrauterine insemination. In the control group, no extra intervention will be done.

Main outcome variables

Biochemical pregnancy and clinical pregnancy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130808014301N3**
Registration date: **2021-09-13, 1400/06/22**
Registration timing: **prospective**

Last update: **2021-09-13, 1400/06/22**

Update count: **0**

Registration date

2021-09-13, 1400/06/22

Registrant information

Name

zahra rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8890 0002

Email address

rezaizah@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of probiotic treatment in infertile women who underwent intrauterine insemination in Yas hospital

Public title

The effect of probiotic treatment in infertile women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Infertile women older than 18 years Candidate for intrauterine insemination History of at least twice failure in intrauterine insemination

Exclusion criteria:
Bacterial vaginitis Withdraw to participate in the study

Age
From **18 years** old

Gender
Female

Phase
3

Groups that have been masked

- Care provider

Sample size

Target sample size: **194**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation rule: First, 97 letters A and 97 letters B are written on special papers that are not marked inside. Then all of them are placed in a bag and for each patient, after obtaining informed consent, a paper is removed randomly and without replacement, and based on the letter written on it, the desired intervention is performed for the patient. In addition, interventions A (intervention group) or B (control group) are determined by a lot.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is performed single-blind, the gynecologist who does intrauterine insemination does not know the patient group.

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

Tehran University of Medical Sciences, School of Medicine, Tehran Province, Tehran, Pour Sina St" to "Tehran University of Medical Sciences, School of Medicine, Tehran Province, Tehran, Pour Sina St

City

Tehran

Province

Tehran

Postal code

1598718311

Approval date

2021-08-09, 1400/05/18

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.529

Health conditions studied

1

Description of health condition studied

Female infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Biochemical pregnancy

Timepoint

Once, two weeks after intrauterine insemination

Method of measurement

B HCG titrate

Secondary outcomes

1

Description

Clinical pregnancy

Timepoint

Once, four weeks after intrauterine insemination

Method of measurement

Pregnancy sac observation in transvaginal ultrasound

Intervention groups

1

Description

Intervention group: Lactatovage suppository will be prescribed once per night two weeks before intrauterine insemination. Then, the patients will be undergone intrauterine insemination.

Category

Treatment - Drugs

2

Description

Control group: Without extra interventions, the patients will be undergone intrauterine insemination.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas Hospital

Full name of responsible person

Dr. Zahra Rezaei

Street address

Yas Hospital, Ostad Nejatolahi Ave., Karimkhan Blvd.

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rezaizah@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice-Dean of Research of Tehran University of Medical Sciences, Dr. Sahraiyen

Street address

Vice-Dean of Research, Tehran University of Medical Sciences, Floor 6, Qods St., Keshavarz Blvd, Tehran, Iran

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1416634793

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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**

Tehran University of Medical Sciences

Full name of responsible person

Zahra Rezaei

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Person responsible for updating data

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Email

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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

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

All data is potentially shareable after unidentified participants

When the data will become available and for how long

After manuscript published

To whom data/document is available

No limitations

Under which criteria data/document could be used

The data is only available to the project manager, Dr. Zahra Rezaei, and any analysis must be done with her opinion.

From where data/document is obtainable

Dr. Zahra Rezaei through email (rezaizah@tums.ac.ir)

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

Any request must be made in writing and accompanied by a proposal with an ethics code under the supervision of Dr. Zahra Rezaei.

Comments