

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Evaluation of the effect of oral metronidazole and levofloxacin on increased IVF success rate after at least two failed IVFs

Protocol summary

Study aim

Determining and comparing the effect of oral treatment with "metronidazole and levofloxacin" in comparison with "placebo" on the increased ivf success rate

Design

A randomized, double-blinding clinical trial, with the parallel groups, Phase 3 on 260 couples

Settings and conduct

In this randomized double-blind clinical trial study, 260 couples with a history of at least two unsuccessful IVF who referred to Beheshti Hospital in Isfahan, will be included in the study and randomly divided into 2 groups. One group will receive antibiotic treatment and the other group will receive a placebo. The IVF result (successful or unsuccessful) will then be recorded and compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria included couples (male and female) with a previous unexplained diagnosis of infertility, a history of at least two previous failed IVFs, no antibiotics in the last trimester or before previous IVFs, no diabetes, and chronic kidney disease in Couples and consent to participate in the study. The exclusion criteria are antibiotic allergy.

Intervention groups

Intervention group: Couples (both men and women) are treated with metronidazole 500 mg oral tablet once every 12 hours for 14 days and levofloxacin 500 mg oral tablet once daily for up to seven days. At the end of the course of antibiotic treatment, IVF will be performed for the couple at the same time as the ovulation of the next cycle. Control group: Couples (both men and women) are treated with two placebo tablet every twelve hours, one for 14 days and one daily for seven days. At the end of the course of antibiotic treatment, IVF will be performed for the couple at the same time as the ovulation of the next cycle.

Main outcome variables

Serum β HCG level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N24**

Registration date: **2021-02-20, 1399/12/02**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-20, 1399/12/02**

Update count: **0**

Registration date

2021-02-20, 1399/12/02

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral metronidazole and levofloxacin on increased IVF success rate after at least two failed IVFs		Secondary Ids
		empty
Public title	The effect of metronidazole and levofloxacin on increased IVF success rate	Ethics committees
Purpose	Treatment	<u>1</u>
Inclusion/Exclusion criteria		Ethics committee
Inclusion criteria:	Couples (male and female) diagnosed with previous unexplained infertility History of at least two previous failed IVFs Do not take antibiotics in the last trimester or before previous IVFs Absence of diabetes and chronic kidney disease in couples Couple consent to participate in the study	Name of ethics committee
Exclusion criteria:	Allergy to the studied antibiotics	Ethics committee of Isfahan University of Medical Sciences
Age	No age limit	Street address
Gender	Both	Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq
Phase	3	City
Groups that have been masked	- Participant - Care provider - Investigator - Data analyser	Isfahan
Sample size	Target sample size: 260	Province
Randomization (investigator's opinion)	Randomized	Isfahan
Randomization description	In this study, 260 eligible couples will be non-randomly selected. Then random numbers are created by computer software "Random Allocation" and are automatically divided into two parts. The relevant codes will be entered in the raw checklists and each of these checklists will be randomly assigned to a patient (a couple) and therefore they will be randomly assigned to one of the two study groups.	Postal code
Blinding (investigator's opinion)	Double blinded	8179964167
Blinding description	In this study, two drugs "metronidazole with levofloxacin" and "placebo" were prepared by a pharmacist with similar shape, color, smell, and size and placed in coded packages, and provided to the researcher. He/She prescribes them without knowing the type of each drug. Also, the person recording the patient's clinical information and the statistical analyst will not be aware of the type of intervention.	Approval date
Placebo	Used	2020-09-15, 1399/06/25
Assignment	Parallel	Ethics committee reference number
Other design features		IR.MUI.MED.REC.1399.490
		Health conditions studied
		<u>1</u>
		Description of health condition studied
		Infertility
		ICD-10 code
		N97.9
		ICD-10 code description
		Female infertility, unspecified
		Primary outcomes
		<u>1</u>
		Description
		Serum β HCG level
		Timepoint
		14 days after IVF
		Method of measurement
		ELISA method
		Secondary outcomes
		empty
		Intervention groups
		<u>1</u>
		Description
		Intervention group: Couples (both men and women) are treated with metronidazole 500 mg oral tablet once every 12 hours for 14 days and levofloxacin 500 mg oral tablet once daily for up to seven days. At the end of the course of antibiotic treatment, IVF will be performed for

the couple at the same time as the ovulation of the next cycle.

Category

Treatment - Drugs

2**Description**

Control group: Couples (both men and women) are treated with two placebo pills every twelve hours, one for 14 days and one daily for seven days. At the end of the course of antibiotic treatment, IVF will be performed for the couple at the same time as the ovulation of the next cycle.

Category

Placebo

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

Shahid Beheshti Hospital

Full name of responsible person

Elham Naghshineh

Street address

Motahari Street.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3234 6338

Fax**Email**

naghshineh@med.mui.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Vice Chancellor for Research, School of Medicine,
Hezar Jarib Street, Isfahan.

City

Isfahan

Province

Isfahan

Postal code

8174673461

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+98 31 3668 8597

Email

dean@med.mui.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Isfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Elham Naghshineh

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Department of Obstetrics and Gynecology, Shahid
Beheshti Hospital.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3234 6338

Email

naghshineh@med.mui.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Elham Naghshineh

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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pariyaalirezai@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Paria Alirezai

Position

Non-faculty specialist physician

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Department of Obstetrics and Gynecology, Shahid
Beheshti Hospital.

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available