

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

Public title

The effect of metronidazole and levofloxacin on increased IVF success rate

Purpose

Treatment

Inclusion/Exclusion criteria

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

Exclusion criteria:

Allergy to the studied antibiotics

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **260**

Randomization (investigator's opinion)

Randomized

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.

Blinding (investigator's opinion)

Double blinded

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.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfahan

Postal code

8179964167

Approval date

2020-09-15, 1399/06/25

Ethics committee reference number

IR.MUI.MED.REC.1399.490

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

Serum β HCG level

Timepoint

14 days after IVF

Method of measurement

ELISA method

Secondary outcomes

empty

Intervention groups

1

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.

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Isfahan

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Isfahan

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8174673461

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+98 31 3668 8597

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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

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Postal code

8174673461

Phone

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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

Gynecology and Obstetrics

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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