Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of oral levofloxacin on refractory chronic endometritis in patients with recurrent implant failure

Protocol summary

Study aim
Determination of the effect of oral levofloxacin on refractory chronic endometritis in patients with recurrent implantation failure
Design
The study is a clinical trial, in parallel and double-blind, which will be performed on 60 people by block stratified randomization.
Settings and conduct
This is a double-blind study in which participants, health professionals, researchers, evaluators do not know whether the patient is receiving medication.
Participants/Inclusion and exclusion criteria
Inclusion criteria included women with chronic endometritis with fetal transfer failure confirmed by histology. Aso exclusion criteria include hypersensitivity to doxycycline and metronidazole and deficiency of glucose-6-phosphate dehydrogenase enzyme.
Intervention groups
The study consists of an intervention group.
Main outcome variables
Endometrial infection resolves after levofloxacin treatment

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220413054524N1**
Registration date: **2022-05-09, 1401/02/19**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-09, 1401/02/19**
Update count: **0**
Registration date
2022-05-09, 1401/02/19

Registrant information
Name
Maryam Nemati
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-04-04, 1401/01/15
Expected recruitment end date
2022-05-21, 1401/02/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of oral levofloxacin on refractory chronic endometritis in patients with recurrent implant failure

Public title
Evaluation of the effect of oral levofloxacin on chronic endometritis in patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Females with chronic endometritis with fetal transfer failure confirmed by histology using histology
Exclusion criteria:
Sensitivity to doxycycline Allergy to metronidazole

Glucose 6 phosphate dehydrogenase deficiency

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible individuals in the method of permutation blocks with a volume of 4 people in 15 blocks that are assigned to one of the intervention or control groups. Endometrial sampling (second sample) will continue until 60 patients with refractory endometritis are available. Patients with endometritis in the second sample of endometrium are randomly divided into two groups of intervention and control.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the drugs are coded A and B. None of the participants, health personnel, researchers, evaluators, and analysts know which drug code and which placebo code.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahre-Kord University of Medical Sciences

Street address

Kashani ave

City

Shahre-Kord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2022-03-09, 1400/12/18

Ethics committee reference number

IR.SKUMS,MED.REC.1400.020

Health conditions studied

1

Description of health condition studied

Endometritis

ICD-10 code

N71.9

ICD-10 code description

Inflammatory disease of uterus, unspecified

Primary outcomes

1

Description

Endometritis

Timepoint

Before the intervention and the next menstrual cycle

Method of measurement

Perform a biopsy

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Use levofloxacin for 7 days and have a biopsy for endometritis in the next menstrual cycle.

Category

Treatment - Drugs

2

Description

Control group: They will receive a placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar hospital

Full name of responsible person

AbdolMajid Taheri

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
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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
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Zahra Bakhiyari
Position
resident
Latest degree
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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
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
Yes - There is 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

Title and more details about the data/document
All potential data can be shared after blinding

When the data will become available and for how long
Six mounts after publishing

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
For research purposes and meta-analysis studies

From where data/document is obtainable
Maryam Nemati, Department of Obstetrics and Gynecology, Hajar Hospital, Parstar St., Shahre-kord

What processes are involved for a request to access data/document
Official letter to the researchers

Comments