

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 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. Also 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38 3222 0016

##### Email address

mary.nemati2022@gmail.com

#### 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

**Street address**

Hajar hospital, Parastar ave

**City**

Shahre-Kord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**  
8816754633  
**Phone**  
+98 38 3222 1943  
**Email**  
Hajar-Hospital@skums.ac.ir

**City**  
Shahre-Kord  
**Province**  
Chahar-Mahal-va-Bakhtiari  
**Postal code**  
8816854633  
**Phone**  
+98 38 3222 1943  
**Email**  
shghyeghbakhtiyari@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Shahre-kord University of Medical Sciences  
**Full name of responsible person**  
Mehreban Sadeghi  
**Street address**  
Kashani ave  
**City**  
Shahre-Kord  
**Province**  
Chahar-Mahal-va-Bakhtiari  
**Postal code**  
8815713471  
**Phone**  
+98 38 3334 2414  
**Email**  
sadeghi@skums.ac.ir

#### 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**  
Medical doctor  
**Other areas of specialty/work**  
Gynecology and Obstetrics  
**Street address**  
Hajar hospital,Parastar ave

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Shahre-kord University of Medical Sciences  
**Full name of responsible person**  
Maryam Nemati Dehkordi  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Gynecology and Obstetrics  
**Street address**  
Hajar hospital,Parastar ave  
**City**  
Shahre-Kord  
**Province**  
Chahar-Mahal-va-Bakhtiari  
**Postal code**  
8816854633  
**Phone**  
+98 38 3222 1943  
**Email**  
mertanem@yahoo.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Shahre-kord University of Medical Sciences  
**Full name of responsible person**  
Shahla Taheri  
**Position**  
Non-faculty specialist physician  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Pathology  
**Street address**  
Hajar hospital,Parastar ave  
**City**  
Shahre-Kord  
**Province**  
Chahar-Mahal-va-Bakhtiari  
**Postal code**  
8816854633  
**Phone**  
+98 38 3222 1943  
**Email**

## 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 months 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