Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

The prophylactic effect of azithromycin and doxycycline in infection caused by hysterosalpingography

Protocol summary

Study aim

Comparison of the effect of oral metronidazole and vaginal probiotics on vaginal microbial flora and investigation of treatment failure in women with bacterial vaginosis.

Design

The present study is a clinical trial without a control group, with parallel groups, double-blind, randomized (using block randomization), phase 3 on 110 patients.

Settings and conduct

In this double-blind randomization clinical trial, women candidates for hysterosalpingography will be divided into two equal groups of azithromycin and doxydoxycycline by block randomization. In the azithromycin group, patients will receive 1 gram of oral azithromycin as a single dose, and in the doxycycline group, doxycycline 100 mg tablets orally twice a day for 5 days. Finally, the two groups are compared in terms of outcomes.

Participants/Inclusion and exclusion criteria

Conditions for inclusion in the study: 18-55-year-old women who are candidates for hysterosalpingography, referring to the obstetrics and gynecology clinic, infertility clinic, Amir-al Mominin Hospital, Arak; Consent to participate in the study. Conditions for inclusion in the study: History of acute Pelvic inflammatory disease within two months prior to Hysterosalpingography; history of gynecological surgery and other transcervical procedures within two months prior to Hysterosalpingography; The use of multiple antibiotics within two months before hysterosalpingography.

Intervention groups

In the azithromycin group, before the hysterosalpingography, the patients in the azithromycin group received a single dose of 1 gram of oral azithromycin, and in the doxycycline group, before the hysterosalpingography, the patients in the doxycycline group received 100 mg of doxycycline twice a day for 5 days

Main outcome variables

Fever, side effects, uterine and cervical infection, chlamydial infection, need to treat pelvic inflammatory disease, Prophylaxis satisfaction.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191104045328N15**
Registration date: **2023-06-20, 1402/03/30**
Registration timing: **prospective**

Last update: **2023-06-20, 1402/03/30**
Update count: **0**

Registration date

2023-06-20, 1402/03/30

Registrant information

Name

Amin Haji seyyed hoseini

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

2023-06-22, 1402/04/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The prophylactic effect of azithromycin and doxycycline in infection caused by hysterosalpingography

Public title

Comparison of the effect of two drugs, azithromycin and doxycycline, on infection after hysterosalpingography

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18-55-year-old women who are candidates for hysterosalpingography, referring to the obstetrics and gynecology clinic, infertility clinic, Amir-al Mominin Hospital, Arak Consent to participate in the study

Exclusion criteria:

History of acute Pelvic inflammatory disease within two months prior to Hysterosalpingography, to prevent incompletely treated or residual active Pelvic inflammatory disease. history of gynecological surgery and other transcervical procedures within two months prior to Hysterosalpingography, to avoid confounding by other gynecological procedures. The use of multiple antibiotics within two months before hysterosalpingography, to identify the exact effect of each of the studied antibiotics without disturbing the interaction of multiple antibiotics.

Age

From **18 years** old to **55 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants will be assigned to two intervention and control groups based on the randomization sequence that will be generated in advance. This sequence is unpredictable and its arrangement is completely random. Block randomization method with 8 blocks will be used to allocate the samples. In this way, using the site www.sealedenvelope.com, blocks of 8 letters A and B are randomly generated based on the sample size. The order of placement of letters A and B in each block from the first block to the last block is considered as a randomization sequence. The production of these blocks and their random sequence is completely done by this site and the researcher does not know how they are sequenced.

Blinding (investigator's opinion)

Double blinded

Blinding description

For this, one group will receive single-dose azithromycin tablets, and the other group will receive a starch tablet that is similar to azithromycin, and in addition, the doxy group of patients received doxycycline, And in the azithromycin group, they will receive a starch tablet similar to doxycycline with the same duration and dose. Therefore, the women participating in the study are not aware of the type of medicine. In addition, for blinding of the second type, the medicines are given to the patients by the respected observer and each patient will be coded. Not informed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

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Province

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3848176941

Approval date

2022-08-28, 1401/06/06

Ethics committee reference number

IR.ARAKMU.REC.1401.161

Health conditions studied

1

Description of health condition studied

Infection after hysterosalpingography

ICD-10 code

N71.0

ICD-10 code description

Acute inflammatory disease of uterus

Primary outcomes

1

Description

Fever

Timepoint

2 weeks after hysterosalpingography

Method of measurement

Thermometer

2

Description

side effects

Timepoint

2 weeks after hysterosalpingography

Method of measurement

Physical history

3

Description

Uterine and cervical infection

Timepoint

2 weeks after hysterosalpingography

Method of measurement

Physical examination

4

Description

Chlamydial infection

Timepoint

2 weeks after hysterosalpingography

Method of measurement

Perform PCR

5

Description

The need to treat pelvic inflammatory disease

Timepoint

2 weeks after hysterosalpingography

Method of measurement

History and physical examination

6

Description

Satisfaction with prophylaxis

Timepoint

2 weeks after hysterosalpingography

Method of measurement

A questionnaire made by the researcher

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Before hysterosalpingography, patients in the azithromycin group receive a single dose of 1 gram of azithromycin.

Category

Treatment - Drugs

2

Description

Intervention group: Before hysterosalpingography, patients in the doxycycline group receive 100 mg of doxycycline twice a day for 5 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Taleghani Hospital, Arak

Full name of responsible person

Dr. Nazila Najdi

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Sponsors / Funding sources

1

Sponsor

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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

Arak 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
Arak University of Medical Sciences

Full name of responsible person
Dr. Nazila Najdi

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.

When the data will become available and for how long
Access will be from 2023/11/20 to 2026/11/20 for 3 years.

To whom data/document is available
University researchers

Under which criteria data/document could be used
Academic researchers or university professors or

students who intend to use the data of this study, after obtaining permission from the relevant people mentioned, can use the information of this study in the field of metallurgical studies or other relevant review studies. In addition, if requested, they can use the information of this study for the prerequisites of their future studies and the existence of questions and ambiguities. Using the information of this study is subject to mentioning the names and logos of the responsible persons in this study.

From where data/document is obtainable

Academic researchers and university professors can make a request to use the data from Dr. Nazila Najdi after contacting the relevant professor by message or email. Dr. Nazila Najdi: Phone: 09183482398 Email: najdinazila@gmail.com Address: Vice Chancellor for Education,Ayatollah Taleghani Hospital, Arak, Iran

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

Letter writing should be done with professors and universities.

Comments