

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of Prophylactic efficacy and side effects of azithromycin versus doxycycline prior to hysterosalpingography in sub fertile women

#### Protocol summary

##### Study aim

Comparison of prophylactic efficacy and side effects of azithromycin against doxycycline in prevention of pelvic inflammatory infection after hysterosalpingography in sub fertile women

##### Design

Clinical trial with control group with parallel method double blind randomization with simplified method phase4 on 180 participants Referred patients received doxycycline on even days and azithromycin on odd days.

##### Settings and conduct

Women who were examined for the cause of infertility were diagnosed by hysterosalpingography. By a method (Double Blind Randomization) two groups were divided, the first group 24 hours before the procedure, 2 doses of oral doxycycline 100 mg / BID Received consumption The second group who underwent prophylaxis with oral azithromycin 1 g oral single dose 24 hours before HSG

##### Participants/Inclusion and exclusion criteria

Inclusion criteria - Women 35-15 years infertile - Do not take any class of antibiotics during the week before the procedure Exclusion criteria History of severe drug allergy to doxycycline and azithromycin (anaphylactic shock, cutaneous rash, and complications leading to hospitalization) 2- Active pelvic inflammation 3- Previously known history of pelvic infection 4- Known case of endometriosis History of ectopic pregnancy 6- History of fallopian tube surgery 7- Pregnancy 8- Severe uterine bleeding

##### Intervention groups

Intervention group: Patients receiving azithromycin  
Control group: patients receiving doxycycline Open in Google Translate

##### Main outcome variables

Pelvic infection :positive : negative

#### General information

##### Reason for update

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT20190219042755N1**

Registration date: **2021-02-06, 1399/11/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-02-06, 1399/11/18**

Update count: **0**

##### Registration date

2021-02-06, 1399/11/18

##### Registrant information

###### Name

Zahra Rezaei

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4489 1643

###### Email address

nz.rezaei4000@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-01-14, 1399/10/25

##### Expected recruitment end date

2021-02-19, 1399/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of Prophylactic efficacy and side effects of azithromycin versus doxycycline prior to

hysterosalpingography in sub fertile women

## Public title

Antibiotic prophylaxis with doxycycline vs azithromycin prior to hysterosalpingography

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Sub fertile women 15-35 year old Do not take any antibiotics during the week before the procedure

### Exclusion criteria:

History of severe drug allergy to doxycycline and azithromycin (anaphylactic shock, cutaneous rash, and complications leading to hospitalization) Active pelvic inflammation Previously known history of pelvic infection Known case of endometriosis History of ectopic pregnancy History of fallopian tube surgery Pregnancy Severe uterine bleeding

## Age

From **15 years** old to **35 years** old

## Gender

Female

## Phase

4

## Groups that have been masked

- Participant
- Data analyser

## Sample size

Target sample size: **180**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple randomization: Patients received doxycycline on even days and azithromycin on odd days

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Participants: Provide tablets in unnamed medicine boxes for patients Data Analyzer: Provide raw data based on code one (azithromycin) and code two (doxycycline)

## 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

Arak. The Great Prophet University Complex.

## City

Arak

## Province

Markazi

## Postal code

3848176341

## Approval date

2019-10-29, 1398/08/07

## Ethics committee reference number

IR.ARAKMU.REC.1399.216

## Health conditions studied

### 1

#### Description of health condition studied

pelvic inflammatory disease

#### ICD-10 code

N73.9

#### ICD-10 code description

Female pelvic inflammatory disease, unspecified

## Primary outcomes

### 1

#### Description

Pelvic inflammatory disease is defined as a clinical diagnosis including fever and chills. Vaginal discharge. Abdominal pain.

#### Timepoint

Evaluation of patients' symptoms for pelvic inflammatory infection 2 weeks after hysterosalpingography and in case of patients with symptoms of pelvic inflammatory infection , Follow up patients for the next 2 weeks after symptoms resolve.

#### Method of measurement

Visit the doctor by phone and check the patient's symptoms and if any of the symptoms are fever and chills, vaginal discharge and hypogastric pain, see a gynecologist and after examining the patient and prescribing appropriate treatment, follow up patients for 2 weeks until complete relief of symptoms

## Secondary outcomes

### 1

#### Description

Drug side effects, nausea and vomiting

#### Timepoint

Within two weeks after hysterosalpingography

#### Method of measurement

Phone call by the doctor and questions from the patient

### 2

#### Description

Drug side effects, diarrhea

#### Timepoint

Within two weeks after hysterosalpingography

#### Method of measurement

Phone call by the doctor and questions from the patient

### 3

#### **Description**

Drug side effects, abdominal pain

#### **Timepoint**

Within two weeks after hysterosalpingography

#### **Method of measurement**

Phone call by the doctor and questions from the patient

## **Intervention groups**

### 1

#### **Description**

Control group: patients treated with doxycycline

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group: patients treated with azithromycin

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Valiasr hospital, valiasr square, arak, iran

##### **Full name of responsible person**

Zahra Rezaei

##### **Street address**

Valiasr hospital, valiasr square, arak ,Iran

##### **City**

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##### **Province**

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##### **Postal code**

5755838149

##### **Phone**

+98 86 3222 2003

##### **Email**

pr\_valieasr@arakmu.ac.ir

##### **Web page address**

<http://arakmu.ac.ir/valasrhos/fa>

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Arak University of Medical Sciences

##### **Full name of responsible person**

Alireza kamali

##### **Street address**

Vice Chancellor for Research and Technology,

Payambar Azam (PBUH) University Complex, Arak  
University of Medical Sciences, Arak city,iran

##### **City**

Arak

##### **Province**

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##### **Postal code**

3848176341

##### **Phone**

+98 86 3417 3645

##### **Email**

alikalaliir@yahoo.com

##### **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**

Zahra Rezaei

##### **Position**

Radiology assistant

##### **Latest degree**

Medical doctor

##### **Other areas of specialty/work**

Radiology

##### **Street address**

Valiasr hospital. next to valiasr square. Arak city, iran

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##### **Postal code**

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## **Person responsible for scientific inquiries**

#### **Contact**

##### **Name of organization / entity**

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**Full name of responsible person**  
Zahra Rezaei  
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Radiology assistant  
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Medical doctor  
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## Person responsible for updating data

### Contact

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3814957558  
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**Email**  
Nz.rezaei4000@gmail.com

## 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

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

All individual data will be published after coding.

### When the data will become available and for how long

Access starts 6 months after the results are published

### To whom data/document is available

All people in the field of medicine and treatment are able to benefit from information

### Under which criteria data/document could be used

There are no access restrictions.

### From where data/document is obtainable

Send email to the author Nz.rezaei4000@gmail.com

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

One week after receiving the email

### Comments