

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 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

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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

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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

Zahra Rezaei

Position

Radiology assistant

Latest degree

Medical doctor

Other areas of specialty/work

Radiology

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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

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