Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Arak
Province
Markazi
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
Markazi
Postal code
3848176341
Phone
+98 86 3417 3645
Email
alikamaliir@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
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Email
Nz.rezaei4000@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person
Zahra Rezaei

Position
Radiology assistant

Latest degree
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nz.rezaei4000@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

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Zahra Rezaei

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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