Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Comparison of the Efficacy of the Single Dose Azithromycin and in Combination with Moxifloxacin Based on the Syndromic and Etiologic Diagnostic Methods on Chlamydial Cervicitis

Protocol summary

Study aim
Determination and comparison of the efficacy of the single dose Azithromycin and in combination with Moxifloxacin Based on the syndromic and etiologic diagnostic methods on chlamydial cervicitis

Design
Clinical trial with control group; individual based; with parallel groups, one blind, randomized, phase 3 of the trial

Settings and conduct
18-35 years old women referring to Booali clinic in Amol with cervicitis complaints if they have inclution criteria, after encoding with random assignment by Random application software are divided into 4 experimental groups and depending on their allocation to each group, they are diagnosed and treated. At 1 and 3 months after the start of treatment, the samples are referred for follow up. Finally, in 120 samples (30 samples per group), according to the appropriate statistical tests, the results of the comparison of each of the four groups and the results of the diagnostic value of both diagnostic methods, efficacy and side effects of the two drugs are studied.

Participants/Inclusion and exclusion criteria
Women aged 18-35; Having just one partner in the last two months; Not intake of drugs that interfere with Azithromycin or Moxifloxacin; Not Pregnancy; Not lactation; Absence of abnormal uterine bleeding

Intervention groups
Control group: Oral Azithromycin and syndromic diagnostic method Intervention group 1: Combination therapy of oral Azithromycin and oral Moxifluxacin and syndromic diagnostic method Intervention group 2: Combination therapy of oral Azithromycin and oral Moxifluxacin and ethiologic diagnostic method; Real-Time PCR Intervention group 3: Oral Azithromycin and ethiologic diagnostic method; Real-Time PCR

Main outcome variables
Status of patient's complaints; Status of clinical findings; lab results

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100130003226N16**
Registration date: **2019-01-16, 1397/10/26**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-16, 1397/10/26**
Update count: **0**

Registration date
2019-01-16, 1397/10/26

Registrant information

Name
Mahrokh Dolatian

Name of organization / entity
Shahid Beheshti University of Medical Scenices

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-22, 1397/09/01

Expected recruitment end date
2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Efficacy of the Single Dose Azithromycin and in Combination with Moxifloxacin Based on the Syndromic and Etiologic Diagnostic Methods on Chlamydial Cervicitis

Public title

Comparison of the Efficacy of the Azithromycin and in Combination with Moxifloxacin on Chlamydial Cervicitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 18-35 Having just one partner in the last two months Married and sexually active Clinical diagnosis of chlamydial cervicitis and confirmation of diagnosis by Real-Time PCR (in the etiological diagnostic group of PCR) Syndrome diagnosis of chlamydial cervicitis includes diagnosis based on a set of symptoms that can be found during the history and examination of the patient (in the diagnostic syndromic group)

Exclusion criteria:

Concomitant use of drugs that interfere with azithromycin or moxifluxacin Having a history of allergy to Quinolones or Macrolides Use of intrauterine device pregnancy and pregnancy intent in the next 3 months lactation participating in other studies and drug use over the past 4 weeks abnormal uterine bleeding

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization Random unit: Individual Randomization Tool: Statistical software

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants do not know in which group are assigned. The drug is delivered to the participants in sealed envelopes

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

University Building No. 2, Sixth Floor, Parvaneh Str., Yemeni Ave, Shahid Chamran Highway

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Province

Tehran

Postal code

1985717443

Approval date

2018-07-29, 1397/05/07

Ethics committee reference number

IR.SBMU. RETECH. REC. 1397. 309

Health conditions studied

1

Description of health condition studied

Chlamydial Cervicitis

ICD-10 code

A56.2

ICD-10 code description

Chlamydial infection of genitourinary tract, unspecified

Primary outcomes

1

Description

status of patient's complaints includes vaginal discharge, abdominal pain, painful intercourse

Timepoint

One month and three month after treatment

Method of measurement

Complaint checklist

2

Description

Status of clinical findings includes swollen and fragile cervix, and mucopurulent secretions

Timepoint

One month and three month after treatment

Method of measurement

Clinical findings check list

3

Description

lab results

Timepoint

One month and three month after treatment

Method of measurement

Nucleic Acid Amplification Test (Polymerase Chain Reaction)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Oral Azithromycin and syndromic diagnostic method. Azithromycin 1 g oral single dose (two 500mg) . Azithromycin can be taken with food, after or before meals. This is Dr Abeidi's Pharmaceutical Drug Company (IRC: 2366570648796929 / GTIN: 06260154636041). Syndromic diagnosis: Detection based on a set of symptoms found during a patient's history and examination

Category

Treatment - Drugs

2

Description

Intervention group: Combination therapy of oral azithromycin and oral moxifloxacin and syndromic diagnostic method. Azithromycin 1 g oral single dose (two 500mg). Moxifloxacin tablets 400 mg daily for 7 days. This pill is manufactured by Drug Pakhsh factories (IRC: 2493594828199352 / GTIN: 06260132430517). On the first day of treatment, oral azithromycin 1000 mg is administered as a single dose. Then the treatment is continued from day two to eight with oral moxifloxacin 400 mg once daily for 7 days. Syndromic diagnosis: Detection based on a set of symptoms found during a patient's history and examination

Category

Treatment - Drugs

3

Description

Intervention group: Combination therapy of oral azithromycin and oral moxifloxacin and ethiologic diagnostic method; Real-Time PCR. Azithromycin 1 g oral single dose (two 500mg) and Moxifloxacin tablets 400 mg daily for 7 days. On the first day of treatment, oral azithromycin 1000 mg is administered as a single dose. Then the treatment is continued from day two to eight with oral moxifloxacin 400 mg once daily for 7 days. Ethiologic Diagnostic Method Real-Time PCR : A liquid-based sample is used for NAAT to study chlamydia.

Category

Treatment - Drugs

4

Description

Intervention group: Oral Azithromycin and ethiologic diagnostic method; Real-Time PCR. Azithromycin 1 g oral single dose (two 500mg). Ethiologic Diagnostic Method Real-Time PCR : A liquid-based sample is used for NAAT to study chlamydia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Booali clinic

Full name of responsible person

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Sponsors / Funding sources

1

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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