

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### A randomized double blind placebo-controlled trial: comparison of azithromycin with doxycycline prophylaxis against leptospirosis in human in an endemic area

#### Protocol summary

##### Summary

Objectives: chemo-prophylaxis in leptospirosis, Design: The study population will include all persons more than 18 y/o, will work in the paddy field(some districts of sari as leptospirosis endemic area in north of Iran) during the study period. Individuals in the paediatric age group will not be included. They will be entered in three groups( azithromycin, doxycycline and placebo group). Sample size will be 90 participants in each group. Researchers and participants are blind to the study and randomization will be upon randomization numbers. Method: Before intervention we will draw sample for IgG antileptospira and positive participants will exclude from study. After randomized selection individuals will receive azithromycin 500mg, doxycycline 200mg weekly and placebo from 1 week before starting work, during and 4 weeks after that in three groups chronologically. During this time all persons will be monitor for any symptoms and signs related to leptospirosis through questionnaire by team members in health center of related place and if any person developed symptom, IgM antileptospira will be check at 2-3 week. Screening test (ELISA) for leptospirosis will be done for all individuals in 3 groups at 6 and 12 weeks of the study too.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015052322383N1**  
Registration date: **2016-06-29, 1395/04/09**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-06-29, 1395/04/09

#### Registrant information

##### Name

Ahmad Alikhani

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 5522 6715

##### Email address

a.alikhani@mazums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

vice chancellor for research, Mazandaran University of Medical Sciences,

#### Expected recruitment start date

2015-05-25, 1394/03/04

#### Expected recruitment end date

2015-10-25, 1394/08/03

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

A randomized double blind placebo-controlled trial: comparison of azithromycin with doxycycline prophylaxis against leptospirosis in human in an endemic area

#### Public title

clinical trial azithromycin versus doxycycline chemoprophylaxis in leptospirosis in farmers

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria All persons residing in endemic area of this disease and will supposed to work in the paddy field after taking a verified consent"; " All persons in the range of 18- 65 years old"; " Negative screening test for leptospirosis "; " Agree to apply the doxycycline / azithromycin / placebo for all the times of paddy work "; " Willing to regular monitoring for clinical manifestation"; " Willing to regular monitoring for three intermittent screening testing"; " Agree to report daily water contact"; " Agree to consult the related physician prior to taking any medication"; " No history of allergies to azithromycin or related compounds"; " No history of allergies to doxycycline or related compounds Exclusion criteria: All persons who have positive first screening test for leptospirosis "; "When the persons have hypersensitivity to azithromycin and doxycycline in history "; " Pregnant women for doxycycline group"; " Severe adverse reaction for example; severe photosensitivity due to doxycycline"; "Severe adverse reaction to azithromycin"; "All persons who don't agree to enroll in the research"; "All persons who don't agree consent form

**Age**

From **18 years** old

**Gender**

Both

**Phase**

4

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **270**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features**

randomization number table

**Secondary Ids****1****Registry name**

-

**Secondary trial Id**

-

**Registration date**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Mazandaran University of Medical Sciences

**Street address**

Jouybar three way, Sari, Mazandaran

**City**

Sari

**Postal code**

48471-91971

**Approval date**

2015-05-19, 1394/02/29

**Ethics committee reference number**

882.IR.MAZUMS.REC.94

**Health conditions studied****1****Description of health condition studied**

leptospirosis

**ICD-10 code**

A27

**ICD-10 code description**

A27.8,A27.9

**Primary outcomes****1****Description**

fever,body pain,red eye,calf pain,icter

**Timepoint**

0.6,12 week for IgG and 2nd week after developing disease for IgM

**Method of measurement**

questionnaire and ELISA

**2****Description**

lab. data:thrombocytopenia.CPK,IgG,IgM

**Timepoint**

during the study, from beginning of prophylaxis and placebo, IgM Antileptospira checking 2-3 weeks after for participants will develop symptoms and IgG checking for all at zero,6 and 12 weeks

**Method of measurement**

questionnaire and ELISA

**Secondary outcomes****1****Description**

nausea,vomiting,esophagitis.photosensitivity

**Timepoint**

Drug consumption periods

**Method of measurement**

Interview

## Intervention groups

### 1

#### Description

intervention group 1 : will receive azithromycin 500mg weekly from 1 week before starting work, during and 4 weeks after that.

#### Category

Prevention

### 2

#### Description

control group :will receive placebo( methyl cellulose crystalline manufactured by Iran daru company)

#### Category

Prevention

### 3

#### Description

intervention group 2: will receive doxycycline 200mg weekly from 1 week before starting work, during and 4 weeks after that.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Razi hospital in Ghaemshahr

##### Full name of responsible person

Dr Zameni

##### Street address

Ghaemshahr, yoosef reza st., Razi hospital

##### City

Ghaemshahr

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research, Mazandaran University of Medical Sciences

##### Full name of responsible person

Dr Esmaeeli

##### Street address

Research Vice Chancellor, Moallem st., Sari, Mazandaran

##### City

Sari

#### Grant name

-

#### Grant code / Reference number

-

#### Is the source of funding the same sponsor

#### organization/entity?

Yes

#### Title of funding source

Vice Chancellor for Research, Mazandaran University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Antimicrobial Resistance Research Center

##### Full name of responsible person

Dr. Zameni

##### Position

Infectious Diseases Assistant

##### Other areas of specialty/work

##### Street address

Razi Hospital, Yoosef Reza st., Ghaemshahr

##### City

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##### Postal code

##### Phone

+98 114221801820

##### Fax

##### Email

pzameni3@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Antimicrobial Resistance Research Center

##### Full name of responsible person

Dr.Zameni

##### Position

Infectious diseases Assistant

##### Other areas of specialty/work

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##### City

Ghaemshahr

##### Postal code

##### Phone

+98 114221801820

##### Fax

##### Email

pzameni3@yahoo.com

##### Web page address

## Person responsible for updating data

### Contact

**Name of organization / entity**

Antimicrobial Resistance Research Center of  
Mazandaran University Of Medical Sciences

**Full name of responsible person**

Dr Alikhani

**Position**

Infectious Diseases Specialist

**Other areas of specialty/work****Street address**

Razi Hospital, Yoosef Reza st., Ghaemshahr

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*