

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 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

Ghaemshahr

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

Street address

Razi Hospital, Yoosef Reza st., Ghaemshahr

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

City

Ghaemshahr

Postal code

4765686143

Phone

+98 11 4221 8020

Fax

+98 11 4221 8011

Email

a.alikhani@mazums.ac.ir

Web page address

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