

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Comparison of effect of levofloxacin +doxycycline with rifampin + doxycycline in treatment and relapse of brucellosis

#### Protocol summary

##### Study aim

comparison the effect of levofloxacin plus doxycyclin with doxycyclin plus rifampin in treatment and recurrence of brucellosis

##### Design

double blinded clinical trial

##### Settings and conduct

study will be done in infectious disease clinics on patients which brucellosis is diagnosed by lab data and clinical finding. drugs are allocated randomly in same boxes

##### Participants/Inclusion and exclusion criteria

inclusion criteria: age more than 18 years with brucellosis exclusion criteria: pregnancy, age under 18 years, side effect, sensitivity to drugs

##### Intervention groups

case group receive levofloxacin 750 mg daily plus doxycycline 100 mg /BD and control group receive doxycycline 100 mg/BD plus 600 mg daily for 2 month.

##### Main outcome variables

fever, body pain, diaphoresis, ESR, CRP, COOMBS WRIGHT, wright, 2ME

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180817040819N1**

Registration date: **2019-02-11, 1397/11/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-02-11, 1397/11/22**

Update count: **0**

##### Registration date

2019-02-11, 1397/11/22

##### Registrant information

##### Name

behzad mohsenpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 3366 4958

##### Email address

behzadmohsenpour@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2020-12-21, 1399/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of effect of levofloxacin +doxycycline with rifampin + doxycycline in treatment and relapse of brucellosis

##### Public title

Double blinded clinical trial

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

All patients older than 18 years with brucellosis

##### Exclusion criteria:

pregnancy history of sensitivity to drug meningitis endocarditis

##### Age

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**Target sample size: **280****Randomization (investigator's opinion)**

Randomized

**Randomization description**

simple randomization :randomization with using of table of randomized numbers. if number 0-4 appear case is allocated in group A and if 5-9 appear the case is allocated in group B.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Doctors and patient are unaware of kinds of drugs , the chief manager is aware if group and drug and the analyse is done with someone unaware of groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids****1****Registry name**

دانشگاه علوم پزشکی سنندج

**Secondary trial Id**

IR.MUK.REC.1397.188

**Registration date**

2018-09-25, 1397/07/03

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

Ethics committee of kurdistan university of medical science

**Street address**

pasdaran Ave

**City**

sanadaj

**Province**

Kurdistan

**Postal code**

6617978743

**Approval date**

2018-12-03, 1397/09/12

**Ethics committee reference number**

IR.MUK.REC.1397.188

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

brucellosis disease

**ICD-10 code**

A23.0

**ICD-10 code description**

Brucellosis due to Brucella melitensis

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

fever

**Timepoint**

1 MONTH, 2 MONTH, SIX MONTH AFTER TREATMENT

**Method of measurement**

by thermometer and patient report

**2****Description**

body pain

**Timepoint**

1 MONTH, 2 MONTH, SIX MONTH AFTER TREATMENT

**Method of measurement**

patient report

**3****Description**

DIAPHORESIS

**Timepoint**

1 MONTH, 2 MONTH, SIX MONTH AFTER TREATMENT

**Method of measurement**

patient report

**4****Description**

diaphoresis

**Timepoint**

1 MONTH, 2 MONTH, SIX MONTH AFTER TREATMENT

**Method of measurement**

patient report

**5****Description**

ESR

**Timepoint**

1 MONTH, 2 MONTH, SIX MONTH AFTER TREATMENT

**Method of measurement**

by laborator

## 6

### Description

CRP

### Timepoint

1 MONTH, 2 MONTH, SIX MONTH AFTER TREATMENT

### Method of measurement

BY laboratoary

## 7

### Description

WRIGHT

### Timepoint

1 MONTH, 2 MONTH, SIX MONTH AFTER TREATMENT

### Method of measurement

agglutination test

## 8

### Description

2ME

### Timepoint

1 MONTH, 2 MONTH, SIX MONTH AFTER TREATMENT

### Method of measurement

agglutination

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: patients with brucellosis who is diagnosed by clinical finding and lab data . patients with compatible sign and symptom ; if have a wright test equal or more than 1/160 is allocated in case group. This group receive levofloxacin 750 mg daily and doxycycline 100 mg twice daily . 1 and 2 month after treatment CBC, ESR,CRP , wright, coombs wright and 2ME will be checked. duration of therapy is 2 month . levofloxacin is produced by ABIDI company and doxycycline is produced by RAZAK company.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: patients with brucellosis who is diagnosed by clinical finding and lab data . patients with compatible sign and symptom ; if have a wright test equal or more than 1/160 is allocated in case group and this group will be treated by doxycycline and rifampin for 2 month. Dosage of doxycycline is 100 mg BD and rifampin 600 mg daily .drugs are produced by RAZEK company . after 1 and 2 mon after treatment clinical sign and symptom and sign will be evaluated and wright, coombs wright and 2ME will be assessed .

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Infectious disease clinic

##### Full name of responsible person

Behzad Mohsenpour

##### Street address

Pasdaran

##### City

Sanandaj

##### Province

Kurdistan

##### Postal code

6617978743

##### Phone

+98 87 3366 4958

##### Email

behzadmohsenpour@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sanandaj University of Medical Sciences

##### Full name of responsible person

ebrahim ghaderi

##### Street address

kurdistan university of medical science, pasdaran Blvd,sanandaj, kurdistan, IRAN

##### City

Sanandaj

##### Province

Kurdistan

##### Postal code

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##### Phone

+98 87 3366 4958

##### Fax

+98 87 3366 4957

##### Email

behzadmohsenpour@yahoo.com

##### Web page address

<http://www.muk.ac.ir/Muk.aspx>

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Sanandaj 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**  
Sanandaj University of Medical Sciences  
**Full name of responsible person**  
Behzad Mohsenpour  
**Position**  
Associate Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Infectious diseases  
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## Person responsible for scientific inquiries

### Contact

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**Position**  
Associate Professor  
**Latest degree**  
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## Person responsible for updating data

### Contact

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Sanandaj University of Medical Sciences  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

medical ethics

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available