# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Comparative study of response to treatment and recurrence of brucellosis in the 4 and 6 week treatment groups with doxycycline, streptomycin and hydroxychloroquine. A single blinded randomised clinical trial.

## Protocol summary

**Study aim**
Comparative study of response to treatment and recurrence of brucellosis in the 4 and 6 week treatment groups with doxycycline, streptomycin and hydroxychloroquine. A single blinded randomised clinical trial.

**Design**
two arm parallel group randomized trial with blinded postoperative care and outcome assessment. Each group has 51 people and a total of 102 people

**Settings and conduct**
Farshchian Hospital, Mirzadeh Eshghi Ave.Hamadan single blinded randomised clinical trial Patients assigned to drug regimens do not know

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: 1-patients with sign and symptoms of brucellosis have Wright test of more than 1/160 and 2ME titer more than 1/80 2-age of 18 years or older 3-Consent to participate in the study Exclusion criteria: Chronic Illnesses Any serious complication of brucellosis

**Intervention groups**
A comparative study of response to treatment and recurrence of brucellosis in two group. In the intervention group, the patient is treated with the standard Doxycycline-Streptomycin (4-week Doxycycline, 3-week Streptomycin) plus hydroxy-chloroquine 400 mg daily for 4 weeks. In the control group, the patient is treated with the standard Doxycycline-Streptomycin (6-week Doxycycline, 3-week Streptomycin) and Hydroxychloroquine 400 mg daily for 6 weeks..

**Main outcome variables**
response to treatment, recurrence, side effects

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20160523028008N4**
Registration date: **2019-07-02, 1398/04/11**
Registration timing: **retrospective**

Last update: **2019-07-02, 1398/04/11**
Update count: **0**

**Registration date**
2019-07-02, 1398/04/11

**Registrant information**

**Name**
Mohammad Faryadras

**Name of organization / entity**
Hamadan University of Medical Sciences

**Country**
Iran (Islamic Republic of)

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+98 81 3428 9706

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-02-20, 1397/12/01

**Expected recruitment end date**
2019-06-22, 1398/04/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparative study of response to treatment and recurrence of brucellosis in the 4 and 6 week treatment groups with doxycycline, streptomycin and hydroxychloroquine. A single blinded randomised clinical trial.

**Public title**
Comparative study of response to treatment and recurrence of brucellosis in the 4 and 6 week treatment groups with doxycycline, streptomycin and hydroxychloroquine.

**Purpose**
Treatment

**Inclusion/Exclusion criteria**
**Inclusion criteria:**
patients with sign and symptoms of brucellosis have Wright test of more than 1/160 and 2ME titer more than 1/80 Age of 18 years or older Consent to participate in the study
**Exclusion criteria:**
being pregnant Chronic Illnesses Any serious complication of brucellosis

**Age**
From **18 years** old to **80 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Participant

**Sample size**
Target sample size: **102**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Randomized

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
Blinding: The patients will not aware of the type of treatment they will receive but the physician who will examine the patents will be aware of the type of treatment. Therefore, the trial will be run as single-blinded.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Research Ethic Committee of Hamadan University of Medical Sciences
**Street address**
Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
**City**
Hamadan
**Province**
Hamadan
**Postal code**
6517838695

**Approval date**
2019-04-27, 1398/02/07

**Ethics committee reference number**
IR.UMSHA.REC.1398.022

## Health conditions studied

### 1

**Description of health condition studied**
Brucellosis

**ICD-10 code**
A23

**ICD-10 code description**
Brucellosis

## Primary outcomes

### 1

**Description**
response to treatment

**Timepoint**
at 1, 4, and 6 months after treatment

**Method of measurement**
through history taking and physical examination

### 2

**Description**
recurrence

**Timepoint**
4 and 6 months after treatmen

**Method of measurement**
Recurrence of the patient's clinical symptoms

## Secondary outcomes

### 1

**Description**
Incidence of probable adverse effects such as hepatitis and visual impairment

**Timepoint**
at 1, 4, and 6 months after treatment

**Method of measurement**
through history taking and physical examination

## Intervention groups

### 1

**Description**
Intervention group: Doxycycline - Streptomycin (4 weeks doxycycline, 3 weeks streptomycin) plus hydroxy chloroquine 400 mg daily for 4 weeks
**Category**
Treatment - Drugs

### 2

**Description**
Control group: Doxycycline - Streptomycin (6 week Doxycycline, 3 weeks Streptomycin) and Hydroxychloroquine 400 mg daily for 6 weeks
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Farshchian Hospital
**Full name of responsible person**
Dr Mohammad Mahdi Majzoobi
**Street address**
Farshchian Hospital, Mirzadeh Eshghi Ave
**City**
Hamdan
**Province**
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**Postal code**
6517838695
**Phone**
+98 81 3838 0717
**Email**
mahdi.majzoobi@umsha.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Hamedan University of Medical Sciences
**Full name of responsible person**
Dr Saeid Bashirian
**Street address**
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
**City**
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s-bashirian@umsha.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Hamedan 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**
Hamedan University of Medical Sciences
**Full name of responsible person**
Dr Mohammad Mahdi Majzoobi
**Position**
Specialist in Infectious Diseases
**Latest degree**
Specialist
**Other areas of specialty/work**
Infectious diseases
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## Person responsible for scientific inquiries

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**Full name of responsible person**
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**Position**
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## Person responsible for updating data

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**Full name of responsible person**
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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**
Sampling has not yet been completed
**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