

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 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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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 treatment

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

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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

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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Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences
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Farshchian Hospital
Position
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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