

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of hydroxychloroquine versus standard drug therapy on the treatment and recurrence of brucellosis: a single blinded randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of hydroxychloroquine versus standard drug therapy on the treatment and recurrence of brucellosis **Design:** A single blinded randomized clinical trial. **Setting and conduct:** All eligible patients with acute or chronic brucellosis who will refer to clinic of Farshchian Hospital during the study period will be enrolled in to the trial. **Inclusion criteria:** (a) patients with sign and symptoms of brucellosis have Wright test of more than 1/160 and 2ME titer more than 1/80; (b) patients with chronic brucellosis who did not responded to standard drug therapy with constant or increased 2ME titer; (c) age of 18 years or older. **Exclusion criteria:** (a) being pregnant; (b) having history of porphyria, psoriasis, degenerative macula, hemolytic diseases, gastrointestinal diseases, neurologic diseases, and G6PD deficiency. **Intervention:** oral hydroxychloroquine 400 mg daily for two months plus standard drug therapy for brucellosis. **Control:** only standard drug therapy for brucellosis. **Primary outcome:** response to treatment based on 2ME titer before treatment and 1, 2, 3, and 5 months later. **Secondary outcome:** Incidence of probable adverse effects such as hepatitis and visual impairment through history taking and physical examination at 1, 2, 3, and 5 months after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406299014N37**

Registration date: **2014-07-04, 1393/04/13**

Registration timing: **na**

Last update:

Update count: **0**

Registration date

2014-07-04, 1393/04/13

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Not enough for processing

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2014-07-22, 1393/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of hydroxychloroquine versus standard drug therapy on the treatment and recurrence of brucellosis: a single blinded randomized clinical trial

Public title

The effect of hydroxychloroquine versus standard drug

therapy on the treatment and recurrence of brucellosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) patients with sign and symptoms of brucellosis have Wright test of more than 1/160 and 2ME titer more than 1/80; (b) patients with chronic brucellosis who did not responded to standard drug therapy with constant or increased 2ME titer; (c) age of 18 years or older. Exclusion criteria: (a) being pregnant; (b) having history of porphyria, psoriasis, degenerative macula, hemolytic diseases, gastrointestinal diseases, neurologic diseases, and G6PD deficiency.

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **176**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: Using balance block randomization with group of four so that every four patients will be randomly assigned to intervention and control groups. This process will be continued until to reach the sample size. Blinding: The patients will not aware of the type of treatment they will receive but the physician who will examine the patients will be aware of the type of treatment. Therefore, the trial will be run as single blinded.

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

Postal code

6517838695

Approval date

2014-05-17, 1393/02/27

Ethics committee reference number

D/P/16/35/9/708

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

before treatment and 1, 2, 3, and 5 months later

Method of measurement

based on 2ME titer

Secondary outcomes

1

Description

Incidence of probable adverse effects such as hepatitis and visual impairment

Timepoint

at 1, 2, 3, and 5 months after treatment

Method of measurement

through history taking and physical examination

Intervention groups

1

Description

oral hydroxychloroquine 400 mg daily for two months plus standard drug therapy for brucellosis

Category

Treatment - Drugs

2

Description

only standard drug therapy for brucellosis

Category

Other

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

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

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Hamadan

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 the Technology, Hamadan
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

Farshchian Hospital

Full name of responsible person

Dr Mohammad Mahdi Majzoobi

Position

Specialist in Infectious Diseases

Person responsible for scientific inquiries

Contact

Name of organization / entity

Farshchian Hospital

Full name of responsible person

Dr Mohammad Mahdi Majzoobi

Position

Specialist in Infectious Diseases

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Web page address

Person responsible for updating data

Contact

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