Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of doxycycline-streptomycin, doxycycline-rifampin and ofloxacin-rifampin in the treatment of brucellosis: a randomized clinical trial

Protocol summary

Summary

Objective: To compare the efficacy of ofloxacin plus rifampin (OR) versus doxycycline plus streptomycin (DS) and doxycycline plus rifampin (DR) regimens in the treatment of brucellosis. Methods: In an open-labeled, randomized clinical trial with repeated measurement, 191 patients with brucellosis were enrolled in the study. Inclusion criteria: Patients with clinical presentations and significant titers of specific antibodies and/or a positive blood culture for Brucella. Exclusion criteria: age less than 17 years, Brucella endocarditis, neurobrucellosis, pregnancy, renal failure, hepatic failure, or a history of treatment for brucellosis in the last six months. The sample size for each group was estimated to be 73 cases. One of the three therapeutic regimens was selected for each patient randomly. During the study period, 28 cases were excluded. Finally, 64 patients received ofloxacin plus rifampin, 62 patients treated with doxycycline plus rifampin, and 65 patients received doxycycline plus streptomycin. All patients received a six week course of therapy and were assessed during the period of therapy in the second, fourth and sixth weeks of therapy by clinical course and complications. They also were followed-up clinically and serologically for six months after the cessation of the therapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101245681N1**
Registration date: **2011-03-29, 1390/01/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-03-29, 1390/01/09

Registrant information

Name
Seyyed Hamid Hashemi

Name of organization / entity
Hamedan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Vice-Chancellor of Research and Technology, Hamedan University of Medical sciences, Hamedan, Iran

Expected recruitment start date
2008-04-21, 1387/02/02

Expected recruitment end date
2010-06-20, 1389/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of doxycycline-streptomycin, doxycycline-rifampin and ofloxacin-rifampin in the treatment of brucellosis: a randomized clinical trial

Public title
Therapeutic regimens for brucellosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: clinical presentations compatible with brucellosis in the presence of significant titers of specific antibodies (standard tube agglutination ≥ 1/160, coomb's test ≥ 1/160, 2-mercaptoetanol ≥ 1-80, or Brucella IgG-ELISA > 12) and/or a positive blood culture for Brucella Exclusion criteria: age under 17 years, brucella endocarditis, neurobrucellosis, pregnancy, renal failure, hepatic failure, a history of treatment for brucellosis in the last six months
Age
From **17 years** old to **65 years** old
Gender
Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **191**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Hamedan University of Medical sciences
Street address
Vice-chancellor of Hamedan University of Medical sciences, Fahmideh St.,
City
Hamedan
Postal code
Approval date
2007-04-28, 1386/02/08
Ethics committee reference number
4109/35/16/پ

Health conditions studied

1

Description of health condition studied
Brucellosis
ICD-10 code
A23
ICD-10 code description
Brucellosis

Primary outcomes

1

Description
Therapeutic failure
Timepoint
6 weeks
Method of measurement
Physical examination

2

Description
Relapse
Timepoint
6 months
Method of measurement
physical examination and 2-ME testing (2-ME>or=1/80)

Secondary outcomes

1

Description
Adverse reaction
Timepoint
2, 4, 6 weeks
Method of measurement
observation

Intervention groups

1

Description
doxycycline 200 mg/daily for six weeks plus streptomycin 1000mg/daily for the first three weeks
Category
Treatment - Drugs

2

Description
ofloxacin 800 mg/daily plus rifampin 15 mg/kg daily for six weeks
Category
Treatment - Drugs

3

Description
doxycycline 200 mg/daily plus rifampin 15 mg/kg daily for six weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina Hospital

Full name of responsible person
Dr. seyyed Hamid Hashemi, associate professor of Infectious Diseases

Street address
Mirzadeh-eshghi St.

City
Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-Chancellor of Research and Technology,Hamedan University of Medical sciences

Full name of responsible person
Dr. Ali Ghaleiha

Street address
Vice-Chancellor of Research and Technology, Shahid Fahmideh ST., Hamedan University of Medical sciences

City
Hamedan

Grant name

Grant code / Reference number

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

Title of funding source
Vice-Chancellor of Research and Technology,Hamedan 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
Hamedan University of Medical sciences

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Position
Academic staff

Other areas of specialty/work

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Infectious Diseases Specialist, Associate Professor

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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