

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison the efficacy of gentamicin for 5 days plus doxycycline for 8 weeks versus streptomycin for 2 weeks plus doxycycline for 45 days in the treatment of human brucellosis

Protocol summary

Summary

Streptomycin plus doxycycline and doxycycline plus rifampin are considered as two optimal regimens endorsed by the WHO for the treatment of brucellosis. Emergence of mycobacterial resistance to rifampin and XDR tuberculosis are reasons for selection of a regimen free of rifampin for the treatment of human brucellosis. Efficacy of gentamicin for 5 days plus doxycycline for 8 weeks was 100% in children with brucellosis. Since the efficacy of this regimen in adult cases of brucellosis has not been determined, the purpose of this study was to compare the efficacy of this regimen versus streptomycin for 2 weeks plus doxycycline for 45 days in the treatment of adult cases of human brucellosis. From April 2005 to September 2008 patients with brucellosis who attended at the Department of Infectious Diseases of Babol Medical University, randomly received gentamicin 5 mg/kg/day at most 240 mg/day for 5 days plus doxycycline 100 mg twice daily for eight weeks (GD group) versus streptomycin 1gr IM for 2 weeks plus the same dose of doxycycline for 45 days (SD group). After treatment all cases were followed for one year. Our exclusion criteria were age of less than 14 years, spondylitis, neurobrucellosis, pregnancy and those received antibiotics more than 2 days. The sample size for each group was estimated 83 cases based on relapse and failure rate of 10% in the SD group and prediction of no relapse and failure of therapy with GD group. The primary outcome was clinical improvement without any adverse effects of drugs.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138708191441N1**
Registration date: **2008-12-07, 1387/09/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2008-12-07, 1387/09/17

Registrant information

Name

Mohammad Reza Hasanjani Roushan

Name of organization / entity

Yahyanejad Hospital, Babol Medical University

Country

Iran (Islamic Republic of)

Phone

+98 11 1222 3594

Email address

mr.roshan@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Babol Medical Research Center, Razi Medical Laboratory center

Expected recruitment start date

2005-04-01, 1384/01/12

Expected recruitment end date

2008-09-01, 1387/06/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the efficacy of gentamicin for 5 days plus doxycycline for 8 weeks versus streptomycin for 2 weeks

plus doxycycline for 45 days in the treatment of human brucellosis

Public title
New regimen of therapy in the treatment of Brucellosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria;all uncomplicated adult patients with brucellosis (except peripheral arthritis,sacroiliitis,epididymoorchitis).Exclusion criteria: age of less than 14 years, spondylitis, neurobrucellosis, pregnancy and receiving antibiotics more than 2 days before enrollment.

Age
From **14 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **166**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
Secondary trial Id
Registration date
2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee
Name of ethics committee
The ethics committee of Babol Medical University
Street address
Gangafroz Avenue,Babol Medical University
City
Babol
Postal code
4717641367
Approval date
2005-05-14, 1384/02/24
Ethics committee reference number

1

Health conditions studied

1

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

Primary outcomes

1

Description
Cure
Timepoint
After completion of therapy
Method of measurement
Improvement of all clinical symptoms and signs

Secondary outcomes

1

Description
Failure of therapy
Timepoint
After completion of treatment
Method of measurement
Persistence of the clinical signs and symptoms of the disease after treatment

2

Description
Relapse
Timepoint
Every three months interval for 12 months after treatment
Method of measurement
Reappearance of the clinical symptoms and signs of brucellosis during follow up period with increasing of the titers of STA or 2ME or isolation of brucella from blood culture either in symptomatic or asymptomatic cases

3

Description
Adverse effects of the drugs
Timepoint
During the course of treatment
Method of measurement
Measurement of BUN, creatinin, audial complaints

Intervention groups
empty

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Infectious Diseases,Yahyanejad Hospital,Babol Medical University

Full name of responsible person

Mohammad Reza Hasanjani Roushan

Street address

Yahyanejad Hospital,Modares Avenue

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Ali Bijani

Street address

Research Center of Babol Medical University,Gangafroz Avenue

City

Babol

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Babol University of Medical Sciences

Proportion provided by this source**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

2

Sponsor

Name of organization / entity

Razi Laboratory

Full name of responsible person

Mohammad Jafar Soleimani Amiri

Street address

Modares Avenue, Razi Laboratory

City

Babol

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Razi Laboratory

Proportion provided by this source**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

Yahyanejad Hospital, Babol Medical University

Full name of responsible person

Mohammad Reza Hasanjani Roushan

Position

Professor and head of the Department of Infectious Diseases

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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