

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of the efficacy of gentamicin for 7 days plus doxycycline for 45 days versus the same regime plus rifampin for 45 days in the treatment of human brucellosis

Protocol summary

Summary

Nowadays doxycycline plus rifampin or doxycycline in combination with an aminoglycoside is used for the treatment of human brucellosis. But in many cases it is observed relapse. The aim of this study was to compare of the efficacy of gentamicin for 7 days plus doxycycline for 45 days versus the same regime plus rifampin for 45 days in the treatment of human brucellosis. It will be investigated Brucella DNA by PCR, before and after treatment. Therefore People with brucellosis are employed. Inclusion criteria included: the patient had not received treatment, and also clinical signs and par clinical signs including, blood cultures, Wright test, 2ME and combs wright, must confirm illness in given. Exclusion criteria included: pregnant women, Children younger than 8 year or endocarditis, meningitis and spondylitis patients. Blood sampling is taken before treatment from responders to evaluate DNA of Brucella bacteria with PCR technique. Patients are randomly divided into two 80 patients groups. The first group receives Gentamicin 4-5mg/kg for a week, Doxycycline 100mg/bid for 45 days and moreover second one receives daily Rifampin 600-900 mg for 45 days. All of examinations will be repeated and compared after 6 weeks and 6 months at the end of treatment, respectively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014041217230N1**

Registration date: **2014-05-06, 1393/02/16**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-05-06, 1393/02/16

Registrant information

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Zahra Moulana

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Research Affairs of Babol University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of gentamicin for 7 days plus doxycycline for 45 days versus the same regime plus rifampin for 45 days in the treatment of human brucellosis

Public title

New regimen of therapy in the treatment of human Brucellosis

Purpose

Treatment

Inclusion/Exclusion criteria

After providing adequate information eligible patients volunteer will be enrolled in the study. Inclusion criteria: Patients who have received no treatment, Clinical signs and positive Blood culture, positive serological tests such as Wright and 2ME and Coombs Wright. Exclusion criteria : pregnant women and children less than 8 years, patients with endocarditis, meningitis or spondylitis , Negative PCR tests are also excluded

Age

From **8 years** old to **130 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

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University Sq Ave, Ganje Afrooz

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Approval date

2014-04-23, 1393/02/03

Ethics committee reference number

304018/11/پ/ژ

Health conditions studied**1****Description of health condition studied**

brucellosis

ICD-10 code

A23.0

ICD-10 code description

Brucellosis due to Brucella melitensis

Primary outcomes**1****Description**

DNA of Brucella bacteria

Timepoint

Three sections: in first day of the study, end of the sixth week, end of the sixth month

Method of measurement

PCR

2**Description**

Brucella bacteria

Timepoint

Three sections: in first day of the study, end of the sixth week, end of the sixth month

Method of measurement

Blood culture

3**Description**

Antibody of serum

Timepoint

Before treatment, 6 weeks after beginning of treatment, 6 months after end of treatment

Method of measurement

Wright test, 2ME, Coombs

Secondary outcomes

empty

Intervention groups**1****Description**

Gentamicin 4-5 mg /kg (IM) for one week and doxycycline 100 mg/bid (oral) for 45 days, plus rifampin 600-900 mg /daily(oral) for 45 days orally.

Category

Treatment - Drugs

2**Description**

Gentamicin 4-5 mg /kg for one week as an injection and doxycycline 100 mg/bid for 45 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital, Babol University of Medical Sciences

Full name of responsible person

Street address

Ganje Afrooze Ave. University SQ

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Ali Bijani

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

Babol 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

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Full name of responsible person

Dr. Mohammad Reza Hassanjani Roshan

Position

Professor and head of the Department of Infectious Diseases

Other areas of specialty/work

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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