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.

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

Health conditions studied

1
Description of health condition studied
Brucellosis

ICD-10 code
ICD-10 A23

ICD-10 code description
Brucella melitensis

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
Reapearance 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
eempty
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
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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

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
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Modares Avenue, Razi Laboratory
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Grant name

Person responsible for general inquiries
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Web page address

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