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 1 gr 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: 0
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

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
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**
Babol University of Medical Sciences

**Grant code / Reference number**
empty

**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**
empty

**Public or private sector**
empty

**Domestic or foreign origin**
empty

**Category of foreign source of funding**
empty

**Country of origin**
empty

**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

**Other areas of specialty/work**
empty

**Street address**
Yahyanejad Hospital, Modares Avenue

**City**
Babol

**Postal code**
4717641367

**Phone**
+98 11 1222 3594

**Fax**
Mr. roshan@mubabol.ac.ir

**Email**
Mr. roshan@mubabol.ac.ir

**Web page address**
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**
Razi Laboratory

**Grant code / Reference number**
empty

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

**Title of funding source**
Razi Laboratory

**Proportion provided by this source**
empty

**Public or private sector**
empty

**Domestic or foreign origin**
empty

**Category of foreign source of funding**
empty

**Country of origin**
empty

**Type of organization providing the funding**
empty

### Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Babol Medical University

**Full name of responsible person**
Mohammad Reza Hasanjani Roushan

**Position**
Professor and head of the Department of Infectious Diseases

**Other areas of specialty/work**
empty

**Street address**
Yahyanejad Hospital, Modares Avenue

**City**
Babol

**Postal code**
empty

**Phone**
+98 11 1222 3594

**Fax**
Mr. roshan@mubabol.ac.ir

**Email**
Mr. roshan@mubabol.ac.ir

**Web page address**
empty
Person responsible for updating data

Contact
Name of organization / entity
Babol Medical University
Full name of responsible person
Mohammad Reza Hasanjani Roushan
Position
Professor and head of the Department of Infectious Diseases
Other areas of specialty/work
Street address
Yahyanejad Hospital, Modares Avenue
City
Babol
Postal code
4717641367
Phone
+98 11 1222 3594
Fax
+98 11 1222 7667

Email
mr.roshan@mubabol.ac.ir
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