

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jul 2026

### Comparison of the efficacy of three drug regimens Doxycycline - Rifampin - Gentamicin, Doxycycline - Rifampin- Ciprofloxacin and Doxycycline - Co-trimoxazole - Gentamicin on relapse of disease in patients with complicated brucellosis: A clinical trial

#### Protocol summary

##### Summary

The aim of this study: Comparison of the efficacy of Doxycycline - Rifampin - Gentamicin, Doxycycline - Rifampin- Ciprofloxacin and Doxycycline - Co-trimoxazole - Gentamicin in patients with complicated brucellosis. Study design: After explaining the purpose of the study and obtaining the informed consent, patients will be randomly allocated into A, B and C groups. Randomization will be performed using random block sizes of 3. The study is randomized, single-center, phase 3 trial. Inclusion criteria: Brucella endocarditis; Neurobrucellosis; OCP consumption; Phenytoin consumption; Brucellosis relapse. Exclusion criteria: Stevens-Johnson Syndrom; Anaphylaxis; Pancreatitis; Pseudomembranous colitis; Renal failure. Sample size: 75 patients are participated in the study with 25 patients in each group. The intervention used in the study: Doxycycline 100 mg PO BID, Rifampicin 600 mg IV daily and PO after discharge, Gentamicin 80 mg IV TDS and Streptomycin 1 gr IM after discharge, Ciprofloxacin 400 mg IV and 500 mg PO BID after discharge and Co-trimoxazole (trimethoprim 80 mg/5ml and sulfamethoxazole 400 mg/5 ml) IV BID and PO after discharge. all regimen will be used for 6 months. Primary outcomes: Relapse

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017052734154N1**  
Registration date: **2017-06-30, 1396/04/09**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-06-30, 1396/04/09

##### Registrant information

###### Name

Razieh Kazemi

###### Name of organization / entity

Islamic Azad University of Shahrood

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 3239 6714

###### Email address

r.kazemi@iau-shahrood.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research and technology, Islamic Azad University of Shahrood

##### Expected recruitment start date

2017-06-22, 1396/04/01

##### Expected recruitment end date

2019-06-22, 1398/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the efficacy of three drug regimens Doxycycline - Rifampin - Gentamicin, Doxycycline - Rifampin- Ciprofloxacin and Doxycycline - Co-trimoxazole - Gentamicin on relapse of disease in patients with complicated brucellosis: A clinical trial

**Public title**

The efficacy of Doxycycline – Rifampin – Gentamicin,  
Doxycycline – Rifampin– Ciprofloxacin and Doxycycline –  
Co-trimoxazole – Gentamicin in complicated brucellosis

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Brucella endocarditis; Neurobrucellosis;  
OCP consumption; Phenytoin consumption; Brucellosis  
relapse Exclusion criteria: Stevens-Johnson Syndrom;  
Anaphylaxis; Pancreatitis; Pseudomembranous colitis;  
Renal failure

**Age**

From **17 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **75**

**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**

Ethics Committee of Islamic Azad University of  
Shahrood

**Street address**

Islamic Azad University of Shahrood, Tehran Blvd,  
Shahrood

**City**

Shahroud

**Postal code**

3613773955

**Approval date**

2016-11-05, 1395/08/15

**Ethics committee reference number**

IR.IAU.SHAHROOD.REC.1395.1

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

Brucellosis

**ICD-10 code**

A23

**ICD-10 code description**

Brucellosis

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

Relaps

**Timepoint**

6 months

**Method of measurement**

Physical examination and Wright>or =1/40 and 2-  
ME>or=1/80

**Secondary outcomes**

empty

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

Intervention group: Doxycycline 100 mg PO BID and  
Rifampicin 600 mg IV daily and PO after discharge and  
Gentamicin 80 mg IV TDS and Streptomycin 1 gr IM after  
discharge. This regimen prescribed for 6 months.

**Category**

Treatment - Drugs

**2****Description**

Intervention group: Doxycycline 100 mg PO BID and  
Rifampicin 600 mg IV daily and PO after discharge and  
Ciprofloxacin 400 mg IV and 500 mg PO BID after  
discharge. This regimen prescribed for 6 months.

**Category**

Treatment - Drugs

**3****Description**

Intervention group: Doxycycline 100 mg PO BID and Co-  
trimoxazole (trimethoprim 80 mg/5ml and  
sulfamethoxazole 400 mg/5 ml IV BID and PO after  
discharge and Gentamicin 80 mg IV TDS and  
Streptomycin 1 gr IM after discharge. This regimen  
prescribed for 6 months.

**Category**

Treatment - Drugs

**Recruitment centers**

1

#### Recruitment center

**Name of recruitment center**

Imam Hossein hospital

**Full name of responsible person**

Raziyeh Kazemi

**Street address**

Imam Hossein Hospital, End of Ayatollah Towhidi  
avenue, Shahroud

**City**

Shahroud

#### Sponsors / Funding sources

1

##### Sponsor

**Name of organization / entity**

Vice chancellor for Research and Technology, Islamic  
Azad University of Shahrood

**Full name of responsible person**

Sahebbali Manafi

**Street address**

Islamic Azad University of Shahroud, Tehran Blvd

**City**

Shahroud

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for Research and Technology, Islamic  
Azad University of Shahrood

**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**

Islamic Azad University of Shahrood

**Full name of responsible person**

Raziyeh Kazemi

**Position**

Medical Student

**Other areas of specialty/work**

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#### Person responsible for scientific inquiries

##### Contact

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Ehsan Nezakati

**Position**

Infectious disease specialist

**Other areas of specialty/work**

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#### Person responsible for updating data

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**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*