

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

Shahrood

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

Sahebal 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

Street address

Islamic Azad University of Shahroud, Tehran Blvd,
Shahroud

City

Shahroud

Postal code

Phone

+98 23 3239 1796

Fax

Email

kazemi.raziyeh95@gmail.com

Web page address

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

Street address

Imam Hossein Hospital, End of Ayatollah Towhidi
avenue

City

Shahroud

Postal code

Phone

+98 23 3239 1796

Fax

Email

nezakati@shmu.ac.ir

Web page address

Person responsible for updating data

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

Street address

Islamic Azad University of Shahrood, Tehran Blvd,
Shahroud

City

Shahroud

Postal code

3613773955

Phone

+98 23 3239 1796

Fax

Email

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