Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Effectiveness of ginseng compared with gentamicin in the improvement of symptoms in patients with brucellosis

Protocol summary

Summary

In a single blind randomized clinical trial all patients referred to outpatient clinics of Valiasr hospital and Emamreza with clinical symptoms and signs of brucellosis according to inclusion and exclusion criteria enrolled to study. Patients eligible for the study after obtaining informed consent were allocated randomly to one of three intervention groups: (A) 55 patients treated with doxycycline (Manufacture of Razak pharmaceutical Company) 200 mg (6 weeks), Rifampin (Manufacture of Alhavy pharmaceutical Company) 600 mg (6 weeks) and Gentamicin (Manufacture of Caspian pharmaceutical Company) 5 mg/kg per day (1 week) B: 55 patients treated with doxycycline 200 mg daily (6 weeks), rifampin 600 mg daily (6 weeks) plus ginseng (Manufacture of Goldaru pharmaceutical Company) 500 mg once daily (1 week) c: 55 patients were treated with doxycycline 200 mg daily (6 weeks) and rifampin 600 mg daily (6 weeks) are given. The patient's clinical response or treatment failure for 6 weeks and for relapse to 6 months after completion of treatment are evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412219855N8**
Registration date: **2015-01-10, 1393/10/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-01-10, 1393/10/20

Registrant information

Name

Aiasghar Farazi

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2014-10-01, 1393/07/09

Expected recruitment end date

2015-06-01, 1394/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of ginseng compared with gentamicin in the improvement of symptoms in patients with brucellosis

Public title

The effect of ginseng in the treatment of brucellosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age over 15 years; Wright titer at least 1/160 and 2ME 1/40; informed consent to participate in the study Exclusion criteria: history of brucellosis in the past 2 years; history of chronic brucellosis; pregnant women; having innate or acquired immunodeficiency; history of allergy to ginseng; local forms of brucellosis infection such as endocarditis, spondylitis, etc.; patients

with advanced or chronic disease of heart, lung, liver and kidney

Age
From **15 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **165**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Arak University of Medical Sciences

Street address
Sardasht, Vice Chancellor for Research

City
Arak

Postal code

Approval date
2014-09-29, 1393/07/07

Ethics committee reference number
93-168-4

Health conditions studied

1

Description of health condition studied
Brucellosis

ICD-10 code
A23

ICD-10 code description
Brucellosis

Primary outcomes

1

Description
Disappearance of fever

Timepoint
Days of 0, 3, 5, 7, 14, 21

Method of measurement
With thermometer

2

Description
Resolve of arthralgia

Timepoint
Days of 0, 3, 5, 7, 14, 21

Method of measurement
Questionnaire

3

Description
Constitutional symptoms

Timepoint
Days of 0, 3, 5, 7, 14, 21

Method of measurement
Questionnaire

4

Description
Decrease of CRP

Timepoint
Days of 0,7, 14, 21, 28, 42

Method of measurement
Latex agglutination test

Secondary outcomes

1

Description
Treatment Failure

Timepoint
End of 6 weeks treatment

Method of measurement
No improvement in clinical symptoms and laboratory tests

2

Description
Relapse

Timepoint
Months of 3, 4, 5, 6, 7, 8

Method of measurement
ecurrence of clinical symptoms and laboratory tests

Intervention groups

1

Description
Intervention group 1: doxycycline 200 mg capsules daily (6 weeks) plus rifampin 600 mg capsules daily (6 weeks) plus Ginseng capsules 500 mg daily (1 week)

Category
Treatment - Drugs

2

Description
Intervention group 2 capsules doxycycline 200 mg (6 weeks) plus rifampin 600 mg once daily (6 weeks) plus gentamicin 5 mg/kg per day (1 week)
Category
Treatment - Drugs

3

Description
Controls: doxycycline 200 mg capsules daily (6 weeks) plus rifampin 600 mg capsules daily (6 weeks)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Street address
City
Arak

2

Recruitment center
Name of recruitment center
Emamreza Clinic
Full name of responsible person
Aliasghar Farazi
Street address
Department of Infectious Disease, School
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Ghazavi
Street address
Sardasht, Vice Chancellor for Research
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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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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