Evaluation of the efficacy of garlic tablet in the treatment of brucellosis compared with rifampin

Protocol summary

Summary
There are different methods of brucellosis treatment. One of them is doxycycline (6 weeks), rifampin (6 weeks), gentamicin (one week) that more than other treatment methods are used. With regard to the importance of the rifampin in the treatment of tuberculosis and high incidence of the brucellosis in the country and the central province and also prevalence of tuberculosis in Iran it is better that use another drug instead of rifampin that have fewer side effects and better tolerance in brucellosis. In a double blind clinical trial study all patients with acute brucellosis that included to study are randomly divided in two groups. In group A treatment is Doxycyclin(6w)+Rifampin(6w)+gentamycin(1w) and in group B treatment is Doxycyclin(6w)+Garlic(6w)+Gentamicin(1w). The patient followed to improve clinical signs include fever, arthralgia, weakness and fatigue and a decrease in CRP, Wright and 2ME titer to six months and compared in two groups. All patients information collected by questionnaire and finally the collected data analyzed by spss (version 19) software.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT201305179855N4
Registration date: 2013-06-02, 1392/03/12
Registration timing: registered while recruiting

Recruitment status
Recruitment complete
Funding source
Arak University of Medical Sciences

Expected recruitment start date
2013-05-22, 1392/03/01
Expected recruitment end date
2013-08-15, 1392/05/24
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the efficacy of garlic tablet in the treatment of brucellosis compared with rifampin

Public title
The effectiveness of garlic tablets in the treatment of brucellosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: patients with clinical symptoms of acute brucellosis; serologic test of Wright at least 1:160 and 2ME of 1:40 exclusion criteria: age less than 8 years; the history of the two past years history of treatment of acute brucellosis; past history of chronic brucellosis; pregnant women; having inherent or acquired immunodeficiency; a history of sensitivity to garlic; Focale forms of brucellosis such as Spondylitis, endocarditis...

Age
From 8 years old to 99 years old

Gender
Both

Phase
N/A

Groups that have been masked
Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double 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, Arak University of Medical Sciences, Arak
City
Arak
Country
Iran (Islamic Republic of)
Postal code

Approval date
2012-10-08, 1391/07/17
Ethics committee reference number
91-134-4

Health conditions studied

1
Description of health condition studied
Brucellosis
ICD-10 code
A49.9
ICD-10 code description
Bacterial infection, unspecified

Primary outcomes

1
Description
clinical sign and symptoms
Timepoint
Days of 0, 7, 21, 42
Method of measurement
physical exam and Questionair

Secondary outcomes

1
Description
Decrease of WBC, ESR, CRP
Timepoint
Days of 0, 7, 21, 42
Method of measurement
Check of WBC, ESR, CRP

2
Description
Decrease of Serologic test
Timepoint
Days of 0, 7, 21, 42
Method of measurement
Check of Wright and 2 ME

Intervention groups

1
Description
In group A treatment is Doxycyclin (6w) + Rifampin (6w) + Gentamycin (1w)
Category
Treatment - Drugs

2
Description
In group B treatment is Doxycyclin (6w) + Garlet (6w) + Gentamicin (1w)
Category
Treatment - Drugs

Recruitment centers

1
Recruitment center
Name of recruitment center
Valiasr hospital in Arak
Full name of responsible person
Aliasghar Farazi
Street address
Department of infectious diseases, Valiasr hospital, Arak, Iran
City
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Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Saed Changizi Ashtyani

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Sardasht, Arak University of Medical Sciences, Arak

City
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Country
Iran (Islamic Republic of)

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
empty

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
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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