Clinical Trial Protocol
Iranian Registry of Clinical Trials
09 Dec 2019

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

Last update:
Update count: 0
Registration date
2013-06-02, 1392/03/12

Registrant information
Name
Aiasghar Farazi
Name of organization / entity
Arak University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone

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
### 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
   - **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 2ME

### 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**: Arak

### Sponsors / Funding sources

1. **Sponsor**
   - **Name of organization / entity**: Arak University of Medical Sciences
   - **Full name of responsible person**: Saed Changizi Ashtyani
   - **Street address**: Sardasht, Arak University of Medical Sciences, Arak
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
Arak University of Medical Sciences
Full name of responsible person
Ghazaleh Akbarifard
Position
Secretary of research Council
Other areas of specialty/work
Street address
Sardasht, Arak, Arak University of Medical Sciences
City
Arak
Postal code
Phone
+98 86 1417 3645
Fax
Email
gakbarifard@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Aliasghar Farazi
Position
Infectious Diseases Specialist
Other areas of specialty/work
Street address
Department of infectious diseases, valiasr hospital, Arak, Iran
City
Arak
Postal code
Phone
00
Fax
Email
farazialiasghar@yahoo.com
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