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 week) 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)+Garlet(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: empty
Update count: 0
Registration date: 2013-06-02, 1392/03/12

Registrant information
Name
Aiasghar Farazi
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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**
No information

**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

**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

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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

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
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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