Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of effect of levofloxacine +doxycycline with rifampin + doxycycline in treatment and relapse of brucellosis

Protocol summary

Study aim
comparison the effect of levofloxacin plus doxycyclin with doxycyclin plus rifampin in treatment and recurrence of brucellosis
Design
double blinded clinical trial
Settings and conduct
study will be done in infectious disease clinics on patients which brucellosis is diagnosed by lab data and clinical finding. drugs are allocated randomly in same boxes
Participants/Inclusion and exclusion criteria
inclusion criteria: age more than 18 years with brucellosis exclusion criteria: pregnancy, age under 18 years, side effect, sensitivity to drugs
Intervention groups
case group receive levofloxacin 750 mg daily plus doxycycline 100 mg /BD and control group receive doxycycline 100 mg/BD plus 600 mg daily for 2 month.
Main outcome variables
fever,body pain, diaphoresis,ESR,CRP,COOMBS WRIGHT,wright, 2ME

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180817040819N1**
Registration date: **2019-02-11, 1397/11/22**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-11, 1397/11/22**
Update count: **0**
Registration date
2019-02-11, 1397/11/22

Registrant information
Name
behzad mohsenpour
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 87 3366 4958
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-12-22, 1397/10/01
Expected recruitment end date
2020-12-21, 1399/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of effect of levofloxacine +doxycycline with rifampin + doxycycline in treatment and relapse of brucellosis

Public title
Double blinded clinical trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients older than 18 years with brucellosis
Exclusion criteria:
pregnancy history of sensitivity to drug meningitis endocarditis
Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **280**

Randomization (investigator's opinion)
Randomized

Randomization description
simple randomization :randomization with using of table of randomized numbers. if number 0-4 appear case is allocated in group A and if 5-9 appear the case is allocated in group B.

Blinding (investigator's opinion)
Double blinded

Blinding description
Doctors and patient are unaware of kinds of drugs , the chief manager is aware if group and drug and the analyse is done with someone unaware of groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
دانشگاه علوم پزشکی سنندج

Secondary trial Id
IR.MUK.REC.1397.188

Registration date
2018-09-25, 1397/07/03

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of kurdistan university of medical science

Street address
pasdaran Ave

City
sanadaj

Province
Kurdistan

Postal code
6617978743

Approval date
2018-12-03, 1397/09/12

Ethics committee reference number
IR.MUK.REC.1397.188

Health conditions studied

1

Description of health condition studied
brucellosis disease

ICD-10 code
A23.0

ICD-10 code description
Brucellosis due to Brucella melitensis

Primary outcomes

1

Description
fever

Timepoint
1 MONTH, 2 MONTH, SIX MONTH AFTER TREATMENT

Method of measurement
by thermometer and patient report

2

Description
body pain

Timepoint
1 MONTH, 2 MONTH, SIX MONTH AFTER TREATMENT

Method of measurement
patient report

3

Description
DIAPHORESIS

Timepoint
1 MONTH, 2 MONTH, SIX MONTH AFTER TREATMENT

Method of measurement
patient report

4

Description
diaphoresis

Timepoint
1 MONTH, 2 MONTH, SIX MONTH AFTER TREATMENT

Method of measurement
patient report

5

Description
ESR

Timepoint
1 MONTH, 2 MONTH, SIX MONTH AFTER TREATMENT

Method of measurement
by laborator

6

Description
CRP
Timepoint
1 MONTH, 2 MONTH, SIX MONTH AFTER TREATMENT
Method of measurement
BY laboratoary

7

Description
WRIGHT
Timepoint
1 MONTH, 2 MONTH, SIX MONTH AFTER TREATMENT
Method of measurement
agglutination test

8

Description
2ME
Timepoint
1 MONTH, 2 MONTH, SIX MONTH AFTER TREATMENT
Method of measurement
agglutination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients with brucellosis who is diagnosed by clinical finding and lab data . patients with compatible sign and symptom ; if have a wright test equal or more than 1/160 is allocated in case group. This group receive levofloxacine 750 mg daily and doxycycline 100 mg twice daily . 1 and 2 month after treatment CBC, ESR,CRP , wright, coombs wright and 2ME will be checked. duration of therapy is 2 month . levofloxacine is produced by ABIDI company and doxycycline is produced by RAZAK company.
Category
Treatment - Drugs

2

Description
Control group: patients with brucellosis who is diagnosed by clinical finding and lab data . patients with compatible sign and symptom ; if have a wright test equal or more than 1/160 is allocated in case group and this group will be treated by doxtcycline and rifampine for 2 month. Dosage of doxycycline is 100 mg BD and rifampine 600 mg daily .drugs are produced by RAZEK company . after 1 and 2 mon after treatment clinical sign and symptom and sign will be evaluated and wright, coombs wright and 2ME will be assessed .
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Infectious disease clinic
Full name of responsible person
Behzad Mohsenpour
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Pasdaran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
ebrahim ghaderi
Street address
kurdistan university of medical science, pasdaran Blvd,sanandaj, kurdistan, IRAN
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Web page address
http://www.muk.ac.ir/Muk.aspx
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sanandaj University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Behzad Mohsenpour

Position

Associate Prefessor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries

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Position

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Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

medical ethics

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available