

Ofloxacin plus rifampicin versus doxycycline plus rifampicin in the treatment of brucellosis: a randomised clinical trial

Submission date
04/06/2004

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
08/06/2004

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
10/08/2007

Condition category
Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Oguz Karabay

Contact details

Izzet Baysal Faculty of Medicine
Infectious Diseases and Clinical Microbiology
Bolu
Türkiye
14280

Additional identifiers

Study information

Scientific Title

Study objectives

The aim of the present study was to investigate the efficacy, adverse effect and cost of ofloxacin plus rifampicin therapy, and doxycycline plus rifampicin therapy and evaluate in the treatment of brucellosis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Brucellosis

Interventions

This study was carried out in the Social Security Duzce Hospital and Abant Izzet Baysal University Duzce Medical School in Turkey. After obtaining informed consent, a detailed medical history was taken from each patient and a complete physical examination was performed.

Patients who met the criteria for entry were randomly assigned to receive in a 1:1 ratio doxycycline plus rifampicin or ofloxacin plus rifampicin:

1. The doxycycline plus rifampicin group had 14 patients who received doxycycline 100 mg twice daily and rifampicin 600 mg once daily for 45 days
2. The ofloxacin plus rifampicin group had 15 patients who received ofloxacin 400 mg once daily and rifampicin 600 mg once daily for 30 days

Patients were hospitalised for at least 10 days at the beginning of treatment in order to monitor clinical response and potential side effects. The patients were assessed and laboratory tests were also performed during the therapy period in the 2nd, 4th, and 6th week of therapy. At the end of therapy, laboratory tests were reassessed at months 1, 2 and 3, as well as whenever clinical symptoms reappeared.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Ofloxacin, rifampicin, doxycycline

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/12/2001

Eligibility

Key inclusion criteria

Patients suspected to have brucella infection on the basis of clinical (fever, limb and back pains, sweating, fatigue, hepatomegaly, splenomegaly, arthritis, sacroileitis, spondylitis, orchitis and headache) and laboratory findings were hospitalised. The diagnosis was based on the presence of signs and symptoms compatible with brucellosis including a positive agglutination titre (greater than or equal to 1/160) and/or a positive culture. All sera obtained from the patients were examined by serial dilution (from 1:10 to 1:1280) using bacterial antigen.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/12/1999

Date of final enrolment

01/12/2001

Locations

Countries of recruitment

Türkiye

Study participating centre

Izzet Baysal Faculty of Medicine

Bolu

Türkiye

14280

Sponsor information

Organisation

Izzet Baysal Faculty of Medicine (Turkey)

ROR

<https://ror.org/01x1kqx83>

Funder(s)**Funder type**

Not defined

Funder Name

Not provided at time of registration

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	23/06/2004		Yes	No