ISRCTN11871179 https://doi.org/10.1186/ISRCTN11871179

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

Submission date	Recruitment status	[_] Prospectively registered
04/06/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/06/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/08/2007	Infections and Infestations	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Brucellosis

Interventions
This study was carried out in the Social Security Duzce Hospital and Abant Izzet Baysal Universty 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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/1999

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
29

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)

Sponsor details
c/o Dr Oguz Karabay
Infectious Diseases and Clinical Microbiolgy
Bolu
Türkiye
14280
+90 374 253 4656 / 4140
drkarabay@yahoo.com

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01x1kqx83

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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