Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Comparison of the efficacy and possible side effects of high and standard doses of rifampin in the treatment of brucellosis, a randomized clinical trial

Protocol summary

Study aim

Comparison of the efficacy and possible side effects of brucellosis treatment at high doses of rifampin with the usual dose of rifampin

Design

A clinical trial with a control group, with parallel, double-blind, randomized groups on 55 patients, a random number table was used for randomization.

Settings and conduct

In the first group, he is treated for eight weeks. The second group is given the first four weeks of doxycycline with rifampin in high dose and the next four weeks of doxycycline with the standard dose.

Participants/Inclusion and exclusion criteria

Inclusion criterias are Age less than 14 years؛Innate or acquired immunodeficiency؛Simultaneous infection with advanced or chronic heart, lung, liver and kidney diseases Pregnancy؛Taking oral contraceptives؛Phenytoin use؛History of receiving anti-brucellosis treatment in a recent month for more than a week؛Infection with local forms of malaria, endocarditis, spondylitis, meningitis, etc.؛Take antibiotics more than 7 days before the visit؛History of doxycycline or rifampin allergy؛General malaise so that the patient is not able to take the medication orally. Exclusion criteria are All patients with brucellosis, whether hospitalized or referred to a clinic, are included in the plan.

Intervention groups

1- Treated with doxycycline 100 mg q 12 h + rifampin 600 mg / day 2- Treated with doxycycline 100 mg q 12h + rifampin 900-1200 mg / day

Main outcome variables

At the end of the second, fourth, sixth, eighth and three months after the end of treatment, patients should be evaluated for intolerance or drug use, drug side effects, the process of improving clinical symptoms and new symptoms. The persistence of the infection or the failure of treatment will be checked.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201015049030N2**
Registration date: **2022-04-12, 1401/01/23**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-12, 1401/01/23**
Update count: **0**

Registration date

2022-04-12, 1401/01/23

Registrant information

Name

Mohammadreza Salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2811

Email address

mr-salehi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-06-20, 1401/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy and possible side effects of high and standard doses of rifampin in the treatment of brucellosis, a randomized clinical trial

Public title

Comparison of the efficacy and possible side effects of high and standard doses of rifampin in the treatment of brucellosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Isolation of Brucella in culture of blood or bone marrow or other body fluids Positive Brucella PCR test in blood and / or body fluids or tissue samples Wright title equal to or greater than 160/1 The title of Combs Wright is at least two levels higher than Wright

Exclusion criteria:

Age less than 14 years- Intrinsic or acquired immunodeficiency Simultaneous with advanced or chronic heart, lung, liver and kidney diseases Pregnancy- Taking oral contraceptives Consumption of phenytoin History of receiving anti-brucellosis treatment in a recent month for more than a week Infection with local forms of malaria, endocarditis, spondylitis, meningitis, etc. Taking antibiotics more than 7 days before the visit History of allergy to doxycycline or rifampin General malaise so that the patient is not able to take medication orally.

Age

From **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **55**

Randomization (investigator's opinion)

Randomized

Randomization description

Restricted randomization method will use block randomization method. Blocking will be used primarily to balance the number of samples allocated in each of the study groups. This has helped the researcher to ensure that in cases where intermediate surveys are needed during sampling, the number of samples allocated to each of the study groups will be equal. The size of all blocks is equal. In this experiment, two groups of 6 blocks (including 3 participants in the intervention group and 3 participants in the control group) will be used. Randomization tools will also be used based on software random allocation software. In order to generate a random sequence, these softwares are able to generate a random sequence by blocking method in addition to simple randomization. For concealment, the concealment allocation method will be used to execute a random sequence on the participants in a way that the assigned group is not known before the individual is assigned. In this method, using envelopes that were opaque sealed, random sequences (envelopes opaque, sealed, numbered sequentially) were recorded on a card and the drugs were placed in the envelopes, respectively. In order to maintain a random sequence, it was necessary to number the envelopes on the outer surface so that the numbering would be done in the same way. Finally, the letter envelopes were sealed and placed inside a box. At the beginning of the intervention and according to the order of entry of the subjects who were eligible to study, one of the envelopes will be opened in order in the group assigned to that participant. , Will be revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

After selecting the samples, none of the participants will be aware of randomization and assignment to groups. Physicians are given a table of pre-coded numbered numbers, and patients are entered into the study in tabular order. Three smaller envelopes will be placed in the envelopes, Containing small envelopes for the intervention group 1- Doxycycline is 100 mg q 12. On this envelope, this sentence is written. This capsule should be taken one morning, two hours after breakfast, and one evening, one hour before dinner, with plenty of water. Do not lie down for an hour after consumption. 2- The second pack contains 600 mg / day of rifampin. This sentence is written on this envelope. Take two Rifampin 300 mg capsules every morning on an empty stomach and do not eat breakfast for an hour. 3- The second pack contains 900-100 mg / day of yampin. On this envelope is written the sentence immediately before bedtime - one capsule in patients weighing 60 kg or less and two capsules in patients weighing more than 60 kg. Containing small envelopes for the control group 1- Doxycycline is 100 mg q 12. On this envelope, this sentence is written. This capsule should be taken one morning, two hours after breakfast, and one evening, one hour before dinner, with plenty of water. Do not lie down for an hour after consumption. 2- The second pack contains 600 mg / day of rifampin. It is written on this envelope that he should take two Rifampin 300 mg capsules every morning on an empty stomach and not eat breakfast for an hour. 3- The third envelope contains a placebo. On this envelope, it is written that this capsule should be taken at night immediately before going to bed (in case of weight of 60 kg or less, one capsule should be taken and weight of more than 60 kg should be taken in two capsules). Therefore, the present study will be double-blind. The envelope will contain the tablets in one shape, color and size and will be delivered to the patient in the package.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Imam Khomeini Hospital Complex

Street address
Keshavarz Blvd

City
Tehran

Province
Tehran

Postal code
۱۴۱۹۷۳۳۱۴۱

Approval date
2020-01-01, 1398/10/11

Ethics committee reference number
IR.TUMS.IKHC.REC.1398.250

Health conditions studied

1

Description of health condition studied
brucellosis

ICD-10 code
A23

ICD-10 code description
Brucellosis

Primary outcomes

1

Description
Response to treatment

Timepoint
The second, fourth, sixth and eighth weeks after starting treatment and up to three months after treatment

Method of measurement
Patients are divided into the following three groups in terms of response to treatment:1- Complete recovery: Complete recovery is considered when the symptoms disappear with treatment and by the end of the follow-up dose, the symptoms do not return and clinical signs are not found in favor of brucellosis.Relapse: It is when the symptoms have disappeared with treatment, but in the one-year follow-up period after the end of treatment, the symptoms have returned.3 - persistence of infection or treatment failure: is when the signs and symptoms of the disease at the end of treatment are still present

Secondary outcomes

1

Description
side effects

Timepoint
The second, fourth, sixth and eighth weeks after starting treatment and up to three months after treatment

Method of measurement
Presence or absence of side effects

2

Description
Wright laboratory test

Timepoint
The second, fourth, sixth and eighth weeks after starting treatment and up to three months after treatment

Method of measurement
Based on the results of the Wright laboratory test

3

Description
Coombs test

Timepoint
The second, fourth, sixth and eighth weeks after starting treatment and up to three months after treatment

Method of measurement
Based on the results of the Coombs laboratory test

Intervention groups

1

Description
Intervention group: Doxycycline treatment 100 mg q 12h + rifampin 900-1200 mg / dayIn this group, the patient is instructed to take two rifampin 300 mg capsules every morning on an empty stomach and not to eat breakfast for an hour.The next dose of rifampin at night immediately before bedtime,For patients weighing 60 kg or less, one 300 mg rifampin capsule- For patients weighing more than 60 kg, two rifampin capsules are 300 mg.In each group, patients are instructed to take 100 mg doxycycline capsules one in the morning, two hours after breakfast, and one in the evening, one hour before dinner with plenty of water, and up to one hour after Do not take doxycycline for a long time.Doxycycline is given in high doses with rifampin in the first four weeks and doxycycline in standard doses in the next four weeks.

Category
Treatment - Drugs

2

Description
Control group: Doxycycline treatment 100 mg q 12 h + rifampin 600 mg / day In this group, the patient is instructed to take two capsules of rifampin 300 mg every

morning on an empty stomach and not to eat breakfast for an hour. Treated for eight weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Mohammad Reza Salehi

Street address

Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2811

Email

salehi.mohamad3@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Salehi

Street address

Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2811

Email

salehi.mohamad3@gmail.com

Web page address

Grant name

Akbar Fotohi

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Salehi

Position

Associate professor of Infectious Diseases

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2811

Email

salehi.mohamad3@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Salehi

Position

Associated Professor of Infectious diseases

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2811

Email

salehi.mohamad3@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mohammed Reza Salehi

Position
Associate Professor of Infectious Diseases

Latest degree
Specialist

Other areas of specialty/work
Infectious diseases

Street address
Keshavarz Blvd

City
Tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6119 2811

Email
salehi.mohamad3@gmail.com

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
There is no more information

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available