Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of vitamin A adjuvant therapy on the decrease of relapse of Brucellosis.

Protocol summary

Study aim
The rate of relapse are determined in the intervention and control group.

Design
Double blind randomized clinical trial with control group. Randomization will be performed based on random numbers. The sample size will be 110 patients in both intervention and control groups. This study will be conducted in the third phase of clinical trial.

Settings and conduct
The study will be conducted at ValiAsr Hospital in Arak. The study will also be doubleblind, and the participating patients and the statistical analyst will be blinded to the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All patients who have positive serologic tests for Brucella. Exclusion criteria: All patientsl with focal complications of Brucellosis include Brucella spondylitis, Brucella endocarditis, and Neurobuccosis. All patients who have any immune deficiency.

Intervention groups
Patients in the control group will receive usual treatment (rifampin 600 mg once daily for 6 weeks and doxycycline with a dose of 100 mg twice daily for 6 weeks) for brucellosis also they will receive placebo daily for 6 weeks. Patients in the intervention group, in addition to receiving the usual treatment for brucellosis, will receive vitamin with a dose of 25,000 units daily for 6 weeks.

Main outcome variables
Relapse.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180815040807N1**
Registration date: **2018-10-28, 1397/08/06**
Registration timing: **registered_while_recruiting**
Last update: **2018-10-28, 1397/08/06**
Update count: **0**

Registration date
2018-10-28, 1397/08/06

Registrant information

Name
nooshin Ahmadvand

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3222 2003

Email address
n.ahmadvand@arakmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-03, 1397/04/12

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of vitamin A adjuvant therapy on the decrease of relapse of Brucellosis.

Public title
Evaluation of the vitamin A on the treatment of Brucellosis.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients who have positive serologic tests for Brucella.

Exclusion criteria:

All patients with focal complications of Brucellosis include Brucella spondylitis, Brucella endocarditis, and Neurobuccosis. All patients who have any immune deficiency.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done in a simple randomization way by using a random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

To perform the blindness of this study, Patients and statistical analyzers of will be blind from the type of group and receiving vitamin A or placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Basij Blv.

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2018-07-02, 1397/04/11

Ethics committee reference number

IR.ARAKMU.REC.1397.106

Health conditions studied

1

Description of health condition studied

Brucellosis

ICD-10 code

A23

ICD-10 code description

Brucellosis

Primary outcomes

1

Description

Relapse

Timepoint

Before the intervention, 1, 3, 6, 12 and 15 months after the intervention.

Method of measurement

Patients will be evaluated for the disease recurrence by measuring antibody titres against brucellosis.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group, in addition to receiving the usual treatment for brucellosis, will receive vitamin with a dose of 25,000 units daily for 6 weeks.

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group will receive usual treatment (rifampin 600 mg once daily for 6 weeks and doxycycline with a dose of 100 mg twice daily for 6 weeks) for brucellosis also they will receive placebo daily for 6 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Valias hospital, arak, Iran.

Full name of responsible person

Noushin ahmadvand

Street address

Emam Khomeini Blvd.

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mohammad arjmandzadegan
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Noushin ahmadvand
Position
Resident of infection disease.
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Nooshin Ahmadvand
Position
Resident
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n.ahmadvand@arakmu.ac.ir

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
Secrecy of patient 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