Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Pre and post treatment level of Regulatory T cells in Brucellosis patients received Gentamicin and Doxycycline with levamisole

Protocol summary

Summary

Levamisole is modulator of immune response. T-reg cell has important role in inhibition of immune response during the infection. So presence of these cells in infection is a sign of progress to chronic disease. This research seeks to find a relationship between the uses of Levamisole with Gentamicin and Doxycycline and presence of T-reg. Therefore People with brucellosis are employed. After providing adequate information eligible volunteered patients will be enrolled in the study. Inclusion criteria: the patient had not received treatment, and also clinical signs and para clinical signs including, blood cultures, Wright test, 2ME and combs wright. Exclusion criteria: pregnant women; children younger than 8 years old; endocarditis, meningitis and spondylitis patients. Blood sampling is taken before treatment from responders to evaluate T-regulatory with flow cytometric technique. Patients are randomly divided into two 30 patients groups. The first group receives Gentamicin 4-5mg/kg for a week, Doxcycycline 100mg/bid for 45 days and moreover second one receives daily levamisole 80 mg for 6 weeks. All of examinations will be repeated and compared after 6 weeks and 6 months at the end of treatment, respectively. All in all, the quantitative existence of T-reg will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042617430N1**
Registration date: **2014-05-12, 1393/02/22**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-05-12, 1393/02/22

Registrant information

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Recruitment status

Recruitment complete

Funding source

Research Affairs of Babol University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pre and post treatment level of Regulatory T cells in Brucellosis patients received Gentamicin and Doxycycline with levamisole

Public title

New regimen of therapy in the treatment of human Brucellosis

Purpose

Treatment

Inclusion/Exclusion criteria

After providing adequate information eligible patients volenteer will be enrolled in the study. Inclusion criteria: the patient had not received treatment, and also clinical

signs and para clinical signs including, blood cultures, Wright test, 2ME and combs wright. Exclusion criteria: pregnant women; children younger than 8 years old; endocarditis, meningitis and spondylitis patients.

Age

From **8 years** old to **139 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Babol University of Medical Sciences

Street address

Ganj Afrooze Ave, University Sq .

City

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Postal code

4717641367

Approval date

2014-04-23, 1393/02/03

Ethics committee reference number

304018/10/ژ/پ

Health conditions studied

1

Description of health condition studied

Brucellosis

ICD-10 code

A23.0

ICD-10 code description

Brucellosis due to Brucella melitensis

Primary outcomes

1

Description

Quantity of regulatory T cells

Timepoint

Before treatment,6 weeks after begining of treatment,6months after end of treatment

Method of measurement

Flow cytometric

2

Description

Brucella bacteria

Timepoint

Before treatment,6 weeks after begining of treatment,6months after end of treatment

Method of measurement

Blood culture

3

Description

Antibody of serum

Timepoint

Before treatment,6 weeks after begining of treatment,6months after end of treatment

Method of measurement

Wright test,2ME,Coombs

Secondary outcomes

empty

Intervention groups

1

Description

Control group :Adminisration Gentamicin 4-5 mg / kg (IM) for a week, Doxcycycline 100 mg/bid (oral) for 45 days

Category

Treatment - Drugs

2

Description

Intervention group: Adminisration Gentamicin 4-5 mg / kg (IM) for a week, Doxcycycline 100 mg/bid (oral) for 45 days and levamisole 80 mg(oral)daily for 6 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol Ayatollah Rohani Hospital

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Sponsors / Funding sources

1

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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
Babol University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty