

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jul 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, Doxycycline 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

###### Name

Soheil Ebrahimpour

###### Name of organization / entity

Babol University of Medical Sciences

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Iran (Islamic Republic of)

###### Phone

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s.ebrahimpour@mubabol.ac.ir

##### 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 volunteer 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

Babol

##### Postal code

4717641367

#### Approval date

2014-04-23, 1393/02/03

#### Ethics committee reference number

304018/10/پ/ژ

## 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, Doxycycline 100 mg/bid (oral) for 45 days

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Adminisration Gentamicin 4-5 mg / kg (IM) for a week, Doxycycline 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

**Full name of responsible person**  
Soheil Ebrahimpour  
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## Person responsible for scientific inquiries

### Contact

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Babol University of Medical Sciences  
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Ali Bijani  
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Ganje Afrooze Ave,University Sq  
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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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## Person responsible for updating data

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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*