

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

**A comparative study between the efficacy of oral Cimetidine and low dose of systemic Meglumine Antimoniate (MA) with standard dose of systemic (MA) in the treatment of syrian cutaneous leishmaniasis patients.**

### Protocol summary

#### Summary

Background: Cutaneous leishmaniasis (CL) is a major world health problem, which is increasing in incidence. It is highly endemic in the north and east Mediterranean regions in the Syrian Arab Republic, with more than 75.9% of all (CL) cases recorded from these regions. Pentavalent antimonials have been considered as standard treatment for leishmaniasis. Use of pentavalent antimonials to treat leishmaniasis is associated with a range of clinical, laboratory and electrocardiographic adverse effects. The aim of this study was to compare the effect of oral Cimetidine and low dose of systemic Meglumine Antimoniate (MA) with standard dose of systemic (MA) in the treatment of Syrian cutaneous leishmaniasis patients. This study was, to our knowledge, the first to show the effect of combination therapy oral Cimetidine and (MA) in the treatment of cutaneous leishmaniasis all over the world. Methods: In this randomized double-blinded placebo-controlled clinical trial, Of 120 suspected (CL) patients referred to the Aleppo University Hospital Clinic, 90 patients with the clinical and parasitological diagnosis of (CL) were recruited and were randomly divided into three treatment groups of 30 subjects each. Group (A) was treated with (MA) 60 mg/kg/day/IM and oral placebo. Groups (B) and (C) received (MA) 30 mg/kg/day/IM and oral Cimetidine 1200 mg/day, (MA) 30 mg/kg/day/IM and oral placebo, respectively. The duration of treatment was 3 weeks for all groups. Informed consent was obtained from all the cases. All the patients were visited every two weeks from the beginning of the trial up to six weeks and then at 8 and 12 weeks. The effectiveness of the treatment was classified in three levels as complete response, partial response and no response. Data were analyzed by SPSS 19 using KI square, Mann-Whitney, Kaplan-Mayer and ANOVA tests.

### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2013123116016N1**  
Registration date: **2014-01-22, 1392/11/02**  
Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2014-01-22, 1392/11/02

#### Registrant information

##### Name

Siavash Mohammadzadeh Shanehsaz

##### Name of organization / entity

Kerman University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 1322 2251

##### Email address

siavash@kmu.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

Aleppo University Hospital

#### Expected recruitment start date

2009-12-01, 1388/09/10

#### Expected recruitment end date

2010-12-01, 1389/09/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

### Scientific title

A comparative study between the efficacy of oral Cimetidine and low dose of systemic Meglumine Antimoniate (MA) with standard dose of systemic (MA) in the treatment of syrian cutaneous leishmaniasis patients.

### Public title

A comparative study between the efficacy of oral Cimetidine and low dose of systemic Meglumine Antimoniate (MA) with standard dose of systemic (MA) in the treatment of syrian cutaneous leishmaniasis patients.

### Purpose

Treatment

### Inclusion/Exclusion criteria

Inclusion criteria: parasitological confirmation; age between 5 to 65 years old; normal values of the liver, kidney, and pancreas function tests and EKG before treatment. Exclusion criteria: contraindication to use (MA); pregnant and lactating women; patients with history of cardiac, renal and hepatic diseases; those under treatment with other drugs during the month prior to commencement of the study.

### Age

From **5 years** old to **65 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **90**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

### 1

#### Registry name

The University of Aleppo

#### Secondary trial Id

1858

#### Registration date

2009-12-13, 1388/09/22

## Ethics committees

### 1

#### Ethics committee

### Name of ethics committee

The University of Aleppo

### Street address

Aleppo-Syria

### City

Aleppo

### Postal code

### Approval date

2009-12-13, 1388/09/22

### Ethics committee reference number

1858

## Health conditions studied

### 1

#### Description of health condition studied

Cutaneous Leishmaniasis

#### ICD-10 code

B55.1

#### ICD-10 code description

Cutaneous leishmaniasis

## Primary outcomes

### 1

#### Description

Diameter of lesion

#### Timepoint

Every two weeks from the beginning of the trial up to six weeks and then at 8 and 12 weeks

#### Method of measurement

Socal Method

## Secondary outcomes

### 1

#### Description

Healing time for lesion

#### Timepoint

Every two weeks from the beginning of the trial up to six weeks and then at 8 and 12 weeks

#### Method of measurement

complete response, partial response and no response

## Intervention groups

### 1

#### Description

Group (A) was treated with (MA) 60 mg/kg/day/IM and oral placebo.

#### Category

Treatment - Drugs

### 2

#### Description

Group (B) received (MA) 30 mg/kg/day/IM and oral

Cimetidine 1200 mg/day.

**Category**

Treatment - Drugs

**3**

**Description**

Group (C) received (MA) 30 mg/kg/day/IM and oral placebo.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Aleppo University Hospital

**Full name of responsible person**

**Street address**

Aleppo

**City**

Aleppo

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

The University of Aleppo

**Full name of responsible person**

Dr. Silva Ishkhanian

**Street address**

Aleppo

**City**

Aleppo

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

The University of Aleppo

**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**

**Contact**

**Name of organization / entity**

Aleppo University Hospital

**Full name of responsible person**

Siavash Mohammadzadeh Shanehsaz

**Position**

MD, Dermatology resident

**Other areas of specialty/work**

**Street address**

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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*