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

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity

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mdsiavash@yahoo.com

Web page address

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