

A comparative study of the efficacy of combination therapy with oral omeprazole and low dose of systemic meglumine antimoniate versus the standard dose of systemic meglumine antimoniate in the treatment of cutaneous leishmaniasis

Submission date 05/03/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 15/06/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/09/2009	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Mohammad Ali Nilfroushzadeh

Contact details
Khoram Street
Skin Diseases and Leishmaniasis Research Center
Isfahan
Iran
81876-98191
+98 (0)31 13373736
nilfroushzadeh@mui.ac.ir

Additional identifiers

Study information

Scientific Title

Study objectives

The effect of oral omeprazole and low dose systemic meglumine antimoniate (MA) is more than the standard dose of systemic meglumine antimoniate in the treatment of cutaneous leishmaniasis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The research has been ethically approved by the Ethical committee of the Skin Diseases and Leishmaniasis Research Center (SDLRC) on 11/02/2003, reference number: 85318

Study design

Double-blind randomised study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cutaneous leishmaniasis

Interventions

Group 1 was treated with intramuscular 60 mg/kg/day glucantime (MA) and placebo for three weeks.

Group 2 was treated with intramuscular 30 mg/kg/day glucantime and 40 mg of the oral omeprazole for three weeks.

Group 3 was treated with intramuscular 30 mg/kg/day glucantime and oral placebo for three weeks

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Omeprazole, meglumine antimoniate (glucantime)

Primary outcome(s)

Healing rate during the course of treatment was more in the groups treated with standard dose glucantime and placebo and low dose glucantime and omeprazole than the group treated with low dose glucantime and placebo ($P < 0.05$).

Key secondary outcome(s)

Combination therapy with oral omeprazole and low dose of glucantime can be used as alternative treatment for leishmaniasis especially in patients with history of cardiac, renal, and hepatic disease.

Patients with cardiac diseases were excluded because of some cardiac effects of the glucantime. However, glucantime is not absolutely contraindicated in patients with cardiac diseases and it can be prescribed with ECG monitoring. The study showed that the use of omeprazole as adjuvant therapy will decrease the dose of glucantime for the treatment of cutaneous leishmaniasis and therefore possibly decrease the risk of cardiac events attributed to the use of full dose of glucantime.

Completion date

28/06/2005

Eligibility

Key inclusion criteria

All of the patients had positive smear for leishman body and have not received any topical or systemic therapy for leishmaniasis. The age of patients was between 7-70 years old.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Patients who were pregnant or lactating and patients with history of cardiac, renal, hepatic diseases or patients with any contraindication for treatment were excluded.

Date of first enrolment

28/06/2004

Date of final enrolment

28/06/2005

Locations

Countries of recruitment

Iran

Study participating centre

Khoram Street
Isfahan
Iran
81876-98191

Sponsor information

Organisation

Skin Diseases and Leishmaniasis Research Center (SDLRC) (Iran)

ROR

<https://ror.org/04waqzz56>

Funder(s)

Funder type

Research organisation

Funder Name

Skin Diseases and Leishmaniasis Research Centre (SDLRC) at the University of Iran (Iran)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2008		Yes	No