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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

Registration date
15/06/2006

Overall study status
Completed

Last Edited
25/09/2009

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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).

Secondary outcome measures
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.

Overall study start date
28/06/2004

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

Age group
Adult

Sex
Both

Target number of participants
150

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
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81876-98191

Sponsor information

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

Sponsor details
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Sponsor type
Research organisation

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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