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Comparison of combination of imiquimod and glucantime with glucantime alone in treatment of acute anthroponotic cutaneous leishmaniasis

Submission date	Recruitment status	[_] Prospectively registered
22/01/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/04/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/12/2008	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
SGS 03/18; IRCT138706111166N1

Study information

Scientific Title

Study objectives
Four weeks treatment with topical imiquimod 5% cream applied 3 times/week will increase the efficacy of 2 weeks treatment with intramuscular injections of 60 mg/kg/day glucantime in the treatment of acute anthroponotic cutaneous leishmaniasis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anthroponotic cutaneous leishmaniasis

Interventions
Group 1: Intramuscular glucantime (meglumine antimonate) 60 mg/kg/day for 14 days plus imiquimod 5% cream applied 3 times/week for 4 weeks
Group 2: Glucantime with the same dosage and duration plus placebo cream 3 times/week for 4 weeks

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Imiquimod, glucantime

Primary outcome(s)
1. The rate of clinical response (clinical cure, improvement, or failure) with the two above mentioned treatment regimens on 4 and 8 weeks after beginning treatment for acute anthroponotic cutaneous leishmaniasis
2. The rate of parasitological cure with the two above mentioned treatment regimens on 4 and 8 weeks after beginning treatment for acute anthroponotic cutaneous leishmaniasis
3. The rate of relapse with the two above mentioned treatment regimens 20 weeks after beginning treatment for acute anthroponotic cutaneous leishmaniasis
4. The rate of adverse events with the two above mentioned treatment regimens for acute anthroponotic cutaneous leishmaniasis

Key secondary outcome(s))

The rate of reduction in the size of lesions with the two above mentioned treatment regimens on 4 and 8 weeks after beginning treatment for acute anthroponotic cutaneous leishmaniasis.

Completion date
30/09/2005

Eligibility

Key inclusion criteria
1. Patients with anthroponotic cutaneous leishmaniasis caused by leishmania tropica
2. Aged 12 to 60 years
3. With less than 5 lesions each less than 5 cm in greatest diameter and duration less than 6 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Pregnant or lactating women
2. Duration of lesions more than 6 months
3. Number of lesions more than 5
4. Lesions greater than 5 cm in their largest diameter
5. History of any full course of standard treatment (antimonials)
6. History of allergy to glucantime
7. Serious systemic illnesses (as judged by the physician)
8. Participation in any drug trials in the last 60 days

Date of first enrolment
01/07/2004

Date of final enrolment
30/09/2005

Locations

Countries of recruitment
Iran

Study participating centre

79 Taleghani Avenue
Tehran
Iran
14166

Sponsor information

Organisation
World Health Organisation - Eastern Mediterranean Regional Office (EMRO) (Egypt)

ROR
https://ror.org/01h4ywk72

Funder(s)

Funder type
Research organisation

Funder Name
World Health Organisation - Eastern Mediterranean Regional Office (EMRO) (Egypt)

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	01/12/2006		Yes	No