

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

Submission date
22/01/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
19/04/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
17/12/2008

Condition category
Infections and Infestations

☐ 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

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

Primary study design

Interventional

Study design

Randomised controlled trial

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