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 [] Statistical analysis plan Registration date Overall study status 19/04/2005 Completed [X] Results [] Individual participant data Last Edited Condition category Infections and Infestations 17/12/2008

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

- 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

Secondary outcome measures

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.

Overall study start date

01/07/2004

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

Age group

Adult

Sex

Both

Target number of participants

120

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)

Sponsor details

P.O.Box 7608 Nasr City Cairo Egypt 11371

Sponsor type

Research organisation

Website

http://www.emro.who.int/

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

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	01/12/2006		Yes	No