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The efficacy and safety of a short course of miltefosine and liposomal amphotericin B for visceral leishmaniasis in India

Submission date	Recruitment status	[_] Prospectively registered
01/10/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/10/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/08/2021	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

ClinicalTrials.gov (NCT)
NCT00371995

Protocol serial number
LEI PDE 0603

Study information

Scientific Title
The efficacy and safety of a short course of miltefosine and liposomal amphotericin B for visceral leishmaniasis in India

Study objectives
Visceral Leishmaniasis (VL) is a parasitological infection caused by Leishmania parasites that infect the reticulo-endothelial system and cause hepato-splenomegaly with pancytopenia. if untreated, there is a mortality rate of almost 100%. Most patients die from intercurrent infections.

Hypothesis:
To evaluate the efficacy and safety of a short course of liposomal amphotericin B in combination with miltefosine for the treatment of visceral leishmaniasis in India.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. World Health Organization research Ethics Review Committee (WHO ERC) on the 13th July 2007 (ref: RPC 209)
2. Ethics Committee of Rajendra Memorial Research Institute of Medical Sciences (RMRI-ICMR) on the 14th August 2007
3. Ethics Committee of Kala Azar Medical Research centre-Muzzaffarpur on the 18th August 2007

Study design
Open multicentre clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Visceral leishmaniasis

Interventions
Liposomal amphotericin B (one injection of 5 mg/kg) then miltefosine for 14 days.

Contact information for Principal Investigators:
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Wabsite: http://www.who.int/tdr

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Miltefosine, liposomal amphotericin B

Primary outcome(s)
1. Final cure rate (initial parasitological cure rate based on splenic or bone marrow aspirate and clinical assessment at 6 months after end of treatment)
2. Initial cure rate (initial parasitological cure rate based on splenic or bone marrow aspirate, and clinical response at end of treatment)
3. Adverse events

Key secondary outcome(s))
No secondary outcome measures

Completion date
30/06/2008

Eligibility

Key inclusion criteria
1. Male and female of age between 2 and 65 years (inclusive)
2. Clinical signs and symptoms compatible with Kala Azar (e.g., fever, splenomegaly, anaemia, leucopenia)
3. Confirmed diagnosis of VL by visualisation of parasites on splenic/bone marrow aspirate
4. Written informed consent from the patient/or from parent or guardian if under 18 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Total final enrolment
135

Key exclusion criteria
1. Haemoglobin less than 6 g/dl
2. White blood cell count less than 1000/mm^3
3. Platelets less than 50,000
4. Prothrombin time greater than 5 seconds above control
5. Aspartate Aminotransferase (ASAT) greater than three times the upper limit of normal
6. Serum creatinine or Blood-Urea Nitrogen (BUN) greater than 1.5 times the upper limit of normal
7. Malaria
8. Human Immunodeficiency Virus (HIV) positive serology
9. Tuberculosis
10. Lactation, pregnancy
11. Refusing contraception method during treatment period plus 3 months
12. Any concomitant drug that is nephrotoxic
13. Previous treatment with amphotericin B or miltefosine. Previous treatment with antimony or paramomycin, if the treatment ended at least 2 months prior and the patient is clinically worsening, is permitted
14. Post Kala-azar Dermal Leishmaniasis (PKDL)
15. Concomitant treatment with other anti-leishmanial drugs
16. Any condition which compromises ability to comply with the study procedures

Date of first enrolment
12/09/2007

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
India

Switzerland

Study participating centre
World Health Organization
Geneva-27
Switzerland
CH-1211

Sponsor information

Organisation
Indian Council of Medical Research (ICMR) (India)

ROR
https://ror.org/0492wrx28

Funder(s)

Funder type
Research organisation

Funder Name
Indian Council of Medical Research (ICMR) (India)

Alternative Name(s)
Indian Council of Medical Research, Government of India, Indian Council of Medical Research (ICMR), New Delhi, ICMROrganisation, , Indian Council of Medical Research, New Delhi, ..., ICMR, ICMRDELHI, ...

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
India

Funder Name
Zentaris GmbH (Germany)

Funder Name
United Nations Children's Fund (UNICEF)/United Nations Development Programme (UNDP)/World Bank/World Health Organization (WHO) - Special Programme for Research and Training in Tropical Diseases (TDR) (ref: LEI PDE 0603)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/12/2010	05/08/2021	Yes	No