

A phase III multicentre, randomised, controlled, clinical trial to assess the safety and efficacy of injectable paromomycin in patients with visceral leishmaniasis (India)

Submission date 05/04/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/06/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/01/2008	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

NCT00216346

Secondary identifying numbers

A20643, A20485, A20648, A20599

Study information

Scientific Title

Study objectives

The aim of this trial is to assess the safety and efficacy of injectable paromomycin in patients with Visceral Leishmaniasis (VL).

Ethics approval required

Old ethics approval format

Ethics approval(s)

The protocol was approved by the independent ethics committee at each of the four participating centers, the Drug Controller General of India, and the Steering Committee on Research Involving Human Subjects of the World Health Organization.

Study design

Randomised controlled trial

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

Visceral leishmaniasis (VL)

Interventions

Intervention group (500 patients):

Injectable paromomycin sulphate 15 mg/kg intramuscular per day x 30 days.

Control group (167 patients):

Injectable amphotericin B 1 mg/kg continuous intravenous infusion every other day, total 15 doses.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Paromomycin, amphotericin B

Primary outcome measure

Safety:

1. Reported adverse events
2. Protocol-defined nephrotoxicity and ototoxicity
3. Laboratory evaluations
4. Vital signs

Secondary outcome measures

Efficacy:

1. Parasite density
2. Final cure
3. Relapse
4. Treatment failure

Overall study start date

23/05/2003

Completion date

30/06/2003

Eligibility**Key inclusion criteria**

1. Aged 5 to 55 years (inclusive) of either gender
2. Confirmed diagnosis by spleen or bone marrow aspirate
3. Clinical signs and symptoms compatible with VL
4. Lab tests:
 - 4.1. Haemoglobin more than 5.0/100 ml
 - 4.2. White Blood Cell (WBC) count more than 1×10^9 l
 - 4.3. Platelet count more than 50×10^9 l
 - 4.4. Aspartate transaminase (AST), alanine transaminase (ALT) and Alkaline Phosphatase less than three times upper normal limit
 - 4.5. Prothrombin time less than five seconds above control
 - 4.6. Serum creatinine within normal limits
 - 4.7. Serum potassium within normal limits
5. Human Immunodeficiency Virus (HIV) negative

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

667

Key exclusion criteria

1. History of intercurrent or concurrent diseases that may introduce variable that affect the outcome of the study
2. Any condition which the investigator thinks may prevent the patient from completing the study therapy
3. An abnormal baseline audiogram and/or a history of vestibular or auditory dysfunction
4. Proteinuria (more than 2 g/day)
5. A history of hypersensitivity or allergy to aminoglycosides
6. History of major surgery within last two weeks
7. Pregnancy or lactation
8. Previous treatment for VL within two weeks of enrolment into the study
9. Prior treatment failures with paromomycin or amphotericin B

Date of first enrolment

23/05/2003

Date of final enrolment

30/06/2003

Locations

Countries of recruitment

India

Switzerland

Study participating centre

20, Avenue Appia

Geneva -27

Switzerland

CH 1211

Sponsor information

Organisation

UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR)

Sponsor details

20, Avenue Appia
Geneva -27
Switzerland
CH 1211

Sponsor type

Research organisation

Website

<http://www.who.int>

ROR

<https://ror.org/01f80g185>

Funder(s)

Funder type

Research organisation

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)

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	21/06/2007		Yes	No