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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

Registration date
07/06/2005

Last Edited
15/01/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

ClinicalTrials.gov (NCT)
NCT00216346

Protocol serial number
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

Study type(s)
Treatment

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(s)
Safety:
1. Reported adverse events
2. Protocol-defined nephrotoxicity and ototoxicity
3. Laboratory evaluations
4. Vital signs

Key secondary outcome(s))
Efficacy:
1. Parasite density
2. Final cure
3. Relapse
4. Treatment failure

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 x 10^9 l
4.3. Platelet count more than 50 x 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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

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

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