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A multicentric, open, comparative, randomized, study to optimize dose, duration, safety, efficacy, and cost of two treatment regimens with liposomal amphotericin (Fungisome) in the treatment of systemic infection in India

Submission date	Recruitment status	[_] Prospectively registered
23/03/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/05/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/01/2021	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SFI

Study information

Scientific Title
A multicentric, open, comparative, randomized, study to optimize dose, duration, safety, efficacy, and cost of two treatment regimens with liposomal amphotericin (Fungisome) in the treatment of systemic infection in India

Study objectives
1. To compare safety, efficacy, duration of treatment and cost of 3 mg/kg/day of liposomal amphotericin (Fungisome) given for a short duration with 1 mg/kg in the previous trial in systemic fungal infections
2. Duration of treatment with Fungisome 3 mg/kg/day versus Fungisome 1 mg/kg/day
3. Total dose given with Fungisome 3 mg/kg/day versus Fungisome 1 mg/kg/day
4. Response time for resolution of symptom and signs of fungal infection
5. Response time for microbiological conversion
6. Total cost of two treatment regimens at the end of study

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Institutional Ethics Committee (IEC) and Institutional Review Board (IRB) of Seth GS Medical College and KEM Hospital, Mumbai, approved on the 9th of December 2005 (ref: EC /GOV-5/2005)
2. The Institutional Ethics Committee of Christian Medical College, Vellore, approved on the 21st of December 2005 (ref: EcMin IRB(EC) 8/12/05)
3. The Institutional Ethics Committee of Nizams Institute of Medical Sciences, Hyderabad, approved on the 16th of December 2005 (ref: 13/1/99/A6)
4. The Institutional Ethics Committee of Post Graduate Institute of Medical Sciences and Research, Chandigarh, approved on the 17th og March 2006 (ref: EC/06-450)
5. The Institutional Ethics Commitee of All India Institute of Medical Research approved on the 10th of March 2006 (ref: A-11: 07/12/2005)

Study design
Multicentre open label comparative randomised study to optimize dose duration safety and efficacy

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
Cryptococcal meningitis

Interventions
Indian liposomal amphotericin B (Fungisome) 3 mg/kg/day versus 1 mg/kg/day)

The proportion of patients for clinical and microbiological response time at day 7 (± standard deviation [SD] 3 days) for Fungisome 1 mg/kg/day is 40% as compared to expected 80% in 3 mg /kg/day. To detect the difference of 40% with an alpha of 0.05 (two sided)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Liposomal amphotericin (Fungisome)

Primary outcome measure
The primary end point is the based on following criteria:
1. Duration of treatment with Fungisome 3 mg/kg/day versus Fungisome 1 mg/kg/day
2. Total dose given with Fungisome 3 mg/kg/day versus Fungisome 1 mg/kg/day
3. Response time for resolution of symptom and signs of fungal infection
4. Response time for microbiological conversion
5. Total Cost of two treatment regimens at the end of study

Secondary outcome measures
The secondary end point is the investigator assessment of overall safety and efficacy of two treatment regimens at the end of therapy

Overall study start date
07/03/2006

Completion date
06/03/2007

Eligibility

Key inclusion criteria
1. Patients with systemic fungal infections must have at least one of the following criteria:
1.1. Cryptococcal meningitis or cryptococcal infections at any other site
1.2.. Documented by typical clinical signs and symptoms and confirmed by cerebral spinal fluid (CSF) culture or tissue culture and/or histology. Culture results may be pending at the time of enrolment, if direct microscopy (India ink preparation) reveals cryptococcal species.

2. Patients and/or legally authorized representative(s), if applicable, have been fully informed and have given written informed consent. A patient unable to write and/or read but who fully understands the oral information given by the investigator (or nominated representative) has given oral informed consent witnessed in writing by an independent person.
3. Patient can be neonates, pediatric patients or adults of either gender (0-28 days, 28 days -18 years and >18 years)
4. Female patients of child bearing potential must have a negative pregnancy test within 14 days prior to first dose of study medication. They must avoid becoming pregnant while receiving study medication by maintaining adequate birth control practice
5. Patients must have sufficient venous access to permit administration of study medication and monitoring of safety variables

29 patients per treatment group are needed in the protocol set to conclude superiority with power of 90%. With an expected rate of 20% drop out, it is planned that 64 patients will be randomised, receiving 8 doses or more who meet eligibility criteria.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
64

Key exclusion criteria
1. Patient is pregnant or nursing
2. Patient with evidence of liver disease as defined by:
2.1. Serum glutamic-oxaloacetic transaminase (SGOT)/aspartate aminotransferase (AST) or serum glutamic pyruvic transaminase (SGPT)/alanine aminotransferase (ALT) >10 times the upper limit of normal (ULN)
2.2. Total bilirubin >5 times ULN
3. Patients whose sole diagnosis is oropharygeal and/or oesophageal candidiasis
4. Patients with history of allergy, hypersensitivity, or any serious reaction to, Fungisome or any product containing amphotericin B
5. Patient previously enrolled into this study
6. Patient participating or having participated in a clinical trial with another investigational drug within the last 28 days except for investigational drugs against cancer, leukaemia or human immunodeficiency virus (HIV)
7. Patients with a concomitant medical condition, whose participation, in the opinion of the investigator, may create an unacceptable additional risk
8. Patients with a life expectancy judged to be less than five days

Date of first enrolment
07/03/2006

Date of final enrolment
06/03/2007

Locations

Countries of recruitment
India

Study participating centre
Department of Clinical Pharmacology
Mumbai
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Sponsor information

Organisation
Government of India (India) - Department of Biotechnology

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Sponsor type
Government

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Funder(s)

Funder type
Government

Funder Name
Government of India (India) - Department of Biotechnology

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	01/04/2010	06/01/2021	Yes	No