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Assessing three day pentamidine for early stage human African trypanosomiasis (Angola)

Submission date	Recruitment status	[_] Prospectively registered
15/04/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/06/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
06/12/2007	Infections and Infestations	[_] Record updated in last year

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
A30765

Study information

Scientific Title

Study objectives
Pharmacokinetic studies have shown that pentamidine has a large volume of distribution and elimination occurs over a long period. The objective of the study is to assess the efficacy of 3 days Intramuscular (IM) pentamidine treatment compared to the standard 7 days IM pentamidine treatment regimen.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. World Health Organization (WHO)/Ethics Review Committee (ERC) on the 4th December 2003
2. Instituto de Combate e Control o Das Triponosommiases (ICCT) (Angola) on the 18th October 2004
3. Wandsworth Local Research Ethics Committee (UK) on the 3rd December 2003

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
Human African Trypanosomiasis (HAT)

Interventions
This will be an open, randomised comparison of two pentamidine treatment regimens, given over three days or seven days with a non-inferiority trial design.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Pentamidine

Primary outcome measure
Proportion of cases with favourable progress at 6 months, based on clinical state and laboratory status.

Secondary outcome measures
1. Proportion of cases with favourable progress at discharge, 3 and 12 months based on clinical state and laboratory status
2. Cure rate at 18 months, based on based on clinical state and laboratory status
3. Frequency and severity of adverse events

Overall study start date
20/12/2004

Completion date
20/12/2006

Eligibility

Key inclusion criteria
1. Aged more than or equal to 14 years and less than 60 years
2. Parasite positive (on examination of lymph juice, by Capillary Tube Centrifugation [CTC] or miniature Anion-Exchange Centrifugation [mAEC] on whole blood)
3. Alternative diagnoses excluded clinically and by appropriate laboratory investigations
4. Capable of and giving informed consent to the study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
The total target was 440 patients, but only 18 were recruited in this site.

Key exclusion criteria
1. Stage II Human African Trypanosomiasis (HAT): defined as parasites in cerebrospinal fluid (CSF), or having more than or equal to 6 cells/mm^3 in CSF; or more than 100 red cells/mm^3 ("bloody tap")
2. Pregnant
3. Previous HAT
4. Known allergy or reactions to pentamidine
5. Diabetes mellitus
6. Difficulty to comply with follow-up (patients of no fixed abode and refugees, for example)

Date of first enrolment
20/12/2004

Date of final enrolment
20/12/2006

Locations

Countries of recruitment
Angola

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
Other

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