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 Infections and Infestations	Individual participant data
06/12/2007		Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Melba Gomes

Contact details

20, Avenue Appia Geneva -27 Switzerland CH 1211 gomesm@who.int

Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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/mm³ in CSF; or more than 100 red cells/mm³ ("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)

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