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Assessing three day pentamidine for first stage human african trypanosomiasis in Uganda

Submission date	Recruitment status	[_] Prospectively registered
14/12/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/12/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/02/2021	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

Protocol serial number
A60914; HAT PDE 06-02

Study information

Scientific Title
Assessing three day pentamidine for first stage human african trypanosomiasis in Uganda

Study objectives

Human African Trypanosomiasis (HAT) occurs in two forms, a generally acute form caused by Trypanosoma brucei rhodesiense and a usually chronic form caused by Trypanosoma brucei gambiense. Its epidemiology is dependent upon conducive environmental factors and the interaction between humans, tsetse flies (glossina) and trypanosomes. The control accordingly involves action on the reservoir and the vector; the specifics though differ for the two forms. For the case of T. b. gambiense, the action on the reservoir (mainly the human host) involves case detection (passively or actively) and chemotherapy with antitrypanosomal agents along with supportive treatment. The current treatment of stage I (also called early or haemolymphatic stage) T.b. gambiense HAT consists of 7 - 10 daily intramuscular injections of pentamidine 4 mg /kg.

Pharmacokinetics studies have shown that pentamidine has a large volume of distribution and elimination occurs over weeks via metabolism, thus allowing the drug to remain in the body over long periods. The currently used regimen for pentamidine in sleeping sickness patients was derived before such pharmacokinetic data were available. With regimen of 7 - 10 days pentamidine intramuscular (IM) (4 mg/kg) currently used in stage I sleeping sickness, pentamidine accumulation occurs to a significant degree. Unsurprisingly, systemic side-effects such as hypoglycaemia are reported to be more common after the first week of such therapy The objective of the study is to compare the efficacy of 3 days IM pentamidine with the standard 7 day IM regimen (both at 4 mg/kg/day).

Please note that the pilot study for this trial was held in Angola and was registered under the following details:
Title: Assessing three day pentamidine for early stage human African trypanosomiasis (Angola)
Registration reference: ISRCTN35617647 (see http://www.controlled-trials.com /ISRCTN35617647)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. Ethical Clearance Committee (Uganda) on the 8th December 2006 (ref: VCD/UNCT 08 12 06)
2. World Health Organization (WHO) Ethics Review Committee (ERC) on the 18th July 2007 (ref: A60914)

Study design
Non-inferiority clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Human African Trypanosomiasis (HAT)

Interventions
1. Three days pentamidine IM at a dose of 4 mg/kg/day
2. Seven days pentamidine IM at a dose of 4 mg/kg/day

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Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Proportion of cases with favourable evolution at 6 months post-treatment, based on laboratory results.

Key secondary outcome(s))
1. Proportion of cases with favourable evolution at the end of treatment assessment (day 10), 3 and 12 months post-treatment, based on laboratory results
2. Cure rate at 18 months post-treatment, based on laboratory results
3. Frequency and severity of adverse events

Completion date
30/06/2011

Eligibility

Key inclusion criteria
1. Age greater than or equal to 10 years and less than 60 years
2. Trypanosome positive lymph node aspirate or blood
3. Consenting patient
4. Alternative diagnoses excluded by appropriate clinical and laboratory investigations

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria

1. Abnormal Cerebrospinal Fluid (CSF):
1.1. CSF White Blood Cell [WBC] count greater than 5 WBC/µl
1.2. Presence of trypanosomes
1.3. Haemorrhagic CSF
2. Pregnant
3. Previous HAT treatment
4. Known allergy or reaction to pentamidine
5. Diabetes mellitus
6. Severe difficulty expected with follow-up. Follow-up is difficult for all patients; only if it appears very probable that a patient will not be able to present for follow-up examinations until 18 months post-treatment should he/she be excluded (e.g. Sudanese refugees who have enrolled in the ongoing voluntary repatriation programme)
7. Patients with severe chronic conditions for whom the chance of survival until the end of the 18 months follow-up period is doubtful (e.g. clinical Human Immunodeficiency Virus [HIV] /Acquired Immune Deficiency Syndrome [AIDS] stage IV and Tuberculosis)

Date of first enrolment
01/12/2007

Date of final enrolment
30/06/2011

Locations

Countries of recruitment
Switzerland

Uganda

Study participating centre
World Health Organization
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	04/07/2009	18/02/2021	Yes	No