

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

<b>Submission date</b> 14/12/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 14/12/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/02/2021	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

## Secondary study design

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet****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

Contact details for Principal Investigator:

Dr Jimmy Opigo

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**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Proportion of cases with favourable evolution at 6 months post-treatment, based on laboratory results.

**Secondary outcome measures**

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

**Overall study start date**

01/12/2007

**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

**Age group**

Not Specified

**Sex**

Both

**Target number of participants**

440

**Key exclusion criteria**

1. Abnormal Cerebrospinal Fluid (CSF):
  - 1.1. CSF White Blood Cell [WBC] count greater than 5 WBC/ $\mu$ l
  - 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)

### **Sponsor details**

20, Avenue Appia  
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### **Sponsor type**

Research organisation

### **Website**

<http://who.int/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**

### **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?
<a href="#">Results article</a>	results	04/07/2009	18/02/2021	Yes	No