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# Clinical study on alternative treatment of patients with second stage Trypanosoma brucei gambiense sleeping sickness

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 09/11/2005 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 16/12/2005 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 31/08/2011 | 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

## Study information

**Scientific Title**

**Study objectives**

The difference in efficacy between classical melarsoprol treatment and alternative treatment regimens is lower than 15%

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Yes. The study protocol was approved by the Ministry of Health, Kinshasa, Democratic Republic of the Congo (DRC) in December 1997.

## Study design
An open randomised trial was designed to test equivalence between standard melarsoprol and 3 other regimens.

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Trypanosoma brucei gambiense Human African Trypanosomiasis in second stage

## Interventions
A. Standard melarsoprol as administered in the DRC: 3 series of 3.6 mg/kg/day intravenously (IV) (maximum 180 mg/day) for 3 days with 7-day breaks in between series. Total dose: 32.4 mg/kg.

B. Concise, consecutive lower-dose melarsoprol: IV during 10 days (0.6 mg/kg on day 1; 1.2 mg /kg on day 2; 1.8 mg/kg from days 3 to 10; maximum 90 mg/day). Total dose: 16.2 mg/kg.

C. Nifurtimox monotherapy: orally, under nurse supervision, 5 mg/kg every 8 hours for 14 days. Total dose: 210 mg/kg.

D. Low-dose concise, consecutive melarsoprol-nifurtimox combination: 2 days melarsoprol alone (0.6 mg/kg on day 1; 1.2 mg/kg on day 2) followed by 8 days 7.5 mg/kg nifurtimox every 12 hours combined with melarsoprol 1.2 mg/kg/day. Total melarsoprol dose: 11.4 mg/kg. Total nifurtimox dose: 120 mg/kg.

## Intervention Type
Drug

## Phase
Not Specified

## Drug/device/biological/vaccine name(s)
Melarsoprol, Nifurtimox

## Primary outcome(s)
Primary outcomes were relapse, severe adverse events and death attributed to treatment.

## Key secondary outcome(s))

Secondary outcomes were frequency of other adverse events

### Completion date
31/05/2001

## Eligibility

### Key inclusion criteria
1, Older than 15 years
2. Second-stage parasitologically confirmed T. b. gambiense infection
3. Never previously treated for sleeping sickness

Second stage disease was defined as: 1° cerebrospinal fluid (CSF) white blood cell (WBC) count >20 /µl and detectable IgM in the CSF; or 2° trypanosomes detected in CSF.

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
1. Glasgow coma scale <8
2. Pregnancy
3. Active tuberculosis
4. Positive syphilis serology
5. Bacterial or cryptococcal meningitis
6. Severe anaemia
7. Severe renal or hepatic dysfunction
8. Hemorrhagic CSF
9. Residence beyond 100 km from Bwamanda Hospital

### Date of first enrolment
01/02/1998

### Date of final enrolment
31/05/2001

## Locations

### Countries of recruitment
Belgium

Congo, Democratic Republic

**Study participating centre**
**Institute of Tropical Medicine**
Antwerpen
Belgium
2000

# Sponsor information

**Organisation**
Institute of Tropical Medicine (Belgium)

**ROR**
https://ror.org/03xq4x896

# Funder(s)

**Funder type**
Research organisation

**Funder Name**
Institute of Tropical Medicine (Belgium)

**Funder Name**
Belgian Directorate-General for Development Co-operation (Belgium)

# 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? |
|---|---|---|---|---|---|
| Abstract results | | 01/02/2007 | | No | No |