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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

Contact name
Prof Philippe Büscher

Contact details
Institute of Tropical Medicine
Department of Parasitology
Nationalestraat 155
Antwerpen
Belgium
2000
+32 (0)3 247 63 71
pbuscher@itg.be

Additional identifiers

Protocol serial number
N/A

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