

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

Submission date
09/11/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
16/12/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
31/08/2011

Condition category
Infections and Infestations

☐ Individual participant data

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

Primary outcomes were relapse, severe adverse events and death attributed to treatment.

Secondary outcome measures

Secondary outcomes were frequency of other adverse events

Overall study start date

01/02/1998

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 / μ l and detectable IgM in the CSF; or 2° trypanosomes detected in CSF.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

600

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)

Sponsor details

Nationalestraat 155

Antwerpen

Belgium

2000

Sponsor type

University/education

Website

<http://www.itg.be>

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

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?
Abstract results		01/02/2007		No	No