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Assessment of an abridged melarsoprol treatment schedule against late stage Trypanosoma brucei rhodesiense sleeping sickness, multinational phase II study (proof of concept)

Submission date	Recruitment status	[X] Prospectively registered
10/03/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/04/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/01/2013	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Johannes Blum

Contact details
Socinstrasse 57
Basel
Switzerland
4002
+41 (0)61 284 8259
johannes.blum@unibas.ch

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
P- 001-05-01-01

Study information

Scientific Title

Acronym
IMPAMEL III

Study objectives
The abridged melarsoprol treatment schedule is safe, tolerable and efficient against second stage Trypanosoma brucei rhodesiense.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics review of the clinical study protocol is ongoing in: Switzerland (Ethics Committee of Basel [EKBB]), Uganda (Ministry of Health) and Tanzania (National Institute for Medical Research [NIMR])

Study design
Multicentre, multinational, non-controlled, phase II study (proof of concept)

Primary study design
Interventional

Secondary study design
Multi-centre

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
T.b. rhodesiense second stage trypanosomiasis

Interventions
New drug treatment schedule for melarsoprol with or without standard pre-treatment with suramin.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Melarsoprol and suramin

Primary outcome measure
1. Efficacy: parasitological and clinical cure 24 hours after treatment
2. Safety: determined by a combined endpoint of serious adverse drug reactions with fatal outcome and other causes of death (e.g. disease-related opportunistic infections). The assessment of safety through the end of treatment evaluation, measurement of vital signs, physical examinations and the use of concomitant medications is included. Adverse events which are spontaneously reported between the end of treatment evaluation and 30 days post-treatment will also be collected.

Secondary outcome measures
Parasitological and clinical cure 3, 6 and 12 months after completion of treatment and relapse, re-infection and death

Overall study start date
01/05/2006

Completion date
31/07/2007

Eligibility

Key inclusion criteria
Patient recruitment through:
1. Active surveillance in high prevalence villages
2. Passive case detection

Inclusion criteria:
1. Patients of either sex with second stage T.b. rhodesiense infection
2. Six years of age or older
3. Must provide written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60 (30 per trial site)

Key exclusion criteria

1. Patients with first stage T.b. rhodesiense infection i.e. presence of trypanosomes in blood upon microscopic examination and no trypanosomes in cerebrospinal fluid (CSF) and/or white blood cell count (WBC) less or equal to 5 cells per mm^3
2. Moribund or unconscious patients at less than 8 points on the Glasgow coma scale
3. Pregnancy
4. Active clinically relevant medical conditions that in the investigators opinion may jeopardise subject safety or interfere with participation in the study, including but not limited to: significant liver disease, chronic pulmonary disease, significant cardiovascular disease, diabetes and open tuberculosis
5. Critically ill patients with any condition which necessitates immediate and concomitant treatment not listed above
6. The subject has been previously enrolled in the study

Date of first enrolment
01/05/2006

Date of final enrolment
31/07/2007

Locations

Countries of recruitment
Switzerland

Tanzania

Uganda

Study participating centre
Socinstrasse 57
Basel
Switzerland
4002

Sponsor information

Organisation
Swiss Tropical Institute (Switzerland)

Sponsor details
Socinstrasse 57
Basel
Switzerland
4002
+41 (0)61 284 8160
d.desavigny@unibas.ch

Sponsor type
Research organisation

Website
http://www.sti.ch

ROR
https://ror.org/03adhka07

Funder(s)

Funder type
Research organisation

Funder Name
Swiss Tropical Institute (Switzerland) - core funding

Funder Name
Swiss Agency for Development and Cooperation (SDC) (Switzerland) - funding for the planning of the trial

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?
Results article	results	01/08/2012		Yes	No