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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
10/03/2006

Registration date
03/04/2006

Last Edited
04/01/2013

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
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])

Primary study design
Interventional

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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
Parasitological and clinical cure 3, 6 and 12 months after completion of treatment and relapse, re-infection and death

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

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

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