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Equivalence trial of tribendimidine versus albendazole against hookworm infections in Ivory Coast

Submission date	Recruitment status	[X] Prospectively registered
21/01/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/01/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
25/08/2011	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PPOOB-102883

Study information

Scientific Title

Acronym
TribenAlben

Study objectives
Tribendimidine is not inferior to albendazole in curing hookworm infections in young adult males

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics review of the clinical trial protocol was conducted by the Minister of Population and Health, Republic of Ivory Coast (Ministere de la Sante et de la Population, Republique de Cote d'Ivoire) and approved according to document number 314/MEMSP/DGPS/DEPS/S-DPM on 20/07/2005

Study design
Curative, randomized, double-blind, equivalence, clinical trial

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
Hookworm infection (Necator americanus and Ancylostoma duodenale)

Interventions
Intervention group: single oral dose of 400 mg tribendimidine
Control group: single oral dose of 400 mg albendazole

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Tribendimidine Albendazole

Primary outcome measure
1. Cure rate at 21 day post-administration
2. Egg reduction rate at 21 day post-administration
3. Observed acute adverse events within 1-3 hours and solicited adverse events within 24 hours

Secondary outcome measures
Rate of perceived illness episodes throughout the 6 months follow-up period with 1 week recall period

Overall study start date
26/01/2006

Completion date
30/09/2006

Eligibility

Key inclusion criteria
Hookworm egg positive adult males (16-45 years) recruited at community survey in the region of Agboville (south Ivory Coast) with written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
450 (225 per treatment group)

Key exclusion criteria
1. Any abnormal medical condition judged by the investigating medical team
2. Hypersensitivity to albendazole or any other anthelmintic drug
3. Taken any anthelmintic drug during the last month before enrolment
4. Hookworm egg negative after 4 Kato-Katz thick smears done on two consecutive stool specimens

Date of first enrolment
26/01/2006

Date of final enrolment

30/09/2006

Locations

Countries of recruitment
Côte d'Ivoire

Study participating centre
Laboratory of Zoology
Abidjan
Côte d'Ivoire
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Sponsor information

Organisation
Swiss Tropical Institute (Switzerland)

Sponsor details
P.O. Box Socinstrasse 57
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Switzerland
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+41 61 2848111
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Sponsor type
Government

Website
http://www.sti.ch

ROR
https://ror.org/03adhka07

Funder(s)

Funder type
Government

Funder Name
Swiss Tropical Institute (core funding)

Funder Name
Swiss National Science Foundation (PPOB-102883)

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

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