

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

Submission date 21/01/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 24/01/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/08/2011	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Eliezer N'Goran

Contact details

Laboratory of Zoology

UFR Biosciences

University of Cocody

22 BP 682

Abidjan

Côte d'Ivoire

22

+225 05 07 65 81

eliezerngoran@yahoo.fr

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

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)

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, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary