Pan African Clinical Trials Registry

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Trial no.:	PACTR202402529220760	**Date of Approval:**	23/02/2024
Trial Status:	Registered in accordance with WHO and ICMJE standards		

TRIAL DESCRIPTION

Public title	REALISE: Real World Evaluation of an Albendazole-Ivermectin Coformulation Safety and Effectiveness
Official scientific title	A Pragmatic Phase III Multi-Centre Clinical Trial to Evaluate the Safety and Effectiveness of a Single Dose of an Albendazole-Ivermectin Coformulation vs Albendazole for Preventive Chemotherapy of Soil-Transmitted Helminth Infections in School-Aged Children
Brief summary describing the background and objectives of the trial	Background: Soil-transmitted helminths (STH) are a group of parasitic worms that cause a major cumulative disease burden worldwide. In the search for safe, efficient and logistically simple solutions to distribute and administer therapeutic alternatives for STH, our group established an international public-private partnership to design and validate innovative products and strategies for the control of STH as a public health problem. The main aim of this consortium is to evaluate a fixed-dose co-formulation (FDC) of IVM and ALB to treat all STH (including S. stercoralis). Study Description: Multi-centric, randomized by school, two-arm, parallel, open-label, pragmatic trial to evaluate the safety and effectiveness of FDC (experimental arm) against ALB (active control arm). The two study arms consist of: - Arm 1: Single dose of a tablet of FDC 400 mg/18 mg IVM or 400 mg ALB/9 mg IVM, administered according to the following age criteria: • For children from 5-14 years old (included) at the time of screening visit: 1 tablet of FDC 400 mg ALB/9 mg IVM • For children from 15-17 years old (included) at the time of screening visit: 1 tablet of FDC 400 mg ALB/18 mg IVM - Arm 2: Single dose of a tablet of ALB 400 mg (active control arm). Objectives: Primary objective - To evaluate and compare the safety of the FDC against ALB via MDA. Secondary objective - To evaluate the effectiveness of one round of MDA with FDC compared to ALB against T. trichiura. Exploratory objectives - To evaluate the effectiveness of one round of MDA with FDC compared to ALB against S. stercoralis by serology. - To evaluate the effectiveness of one round of MDA with FDC compared to ALB against hookworm. - To evaluate the effectiveness of one roun
Type of trial	RCT
Acronym (If the trial has an acronym then please provide)	REALISE
Disease(s) or condition(s) being studied	Infections and Infestations,Paediatrics
Sub-Disease(s) or condition(s) being studied	Soil-transmitted helminths
Purpose of the trial	Treatment: Drugs
Anticipated trial start date	01/07/2024
Actual trial start date	
Anticipated date of last follow up	30/09/2025
Actual Last follow-up date	
Anticipated target sample size (number of participants)	20000
Actual target sample size (number of participants)	
Recruitment status	Not yet recruiting
Publication URL	

Secondary Ids	Issuing authority/Trial register

STUDY DESIGN

Intervention assignment	Allocation to intervention	If randomised, describe how the allocation sequence was generated	Describe how the allocation sequence/ code was concealed from the person allocating the participants to the intervention arms	Masking	If masking / blinding was used
Parallel: different groups receive different interventions at same time during study	Randomised	Permuted block randomization	Allocation was determined by the holder of the sequence who is situated off site	Open-label(Masking Not Used)	

INTERVENTIONS

Intervention type	Intervention name	Dose	Duration	Intervention description	Group size	Nature of control
Control Group	Albendazole	400 mg	Single dose	Single dose of a tablet of ALB 400 mg (active control arm).	10000	Active-Treatment of Control Group
Experimental Group	FDC Albendazole and Ivermectin	400 mg/18 mg IVM or 400 mg ALB/9 mg IVM	Single dose	Single dose of a tablet of FDC 400 mg/18 mg IVM or 400 mg ALB/9 mg IVM, administered according to the following age criteria: • For children from 5-14 years old (included) at the time of screening visit: 1 tablet of FDC 400 mg ALB/9 mg IVM • For children from 15-17 years old (included) at the time of screening visit: 1 tablet of FDC 400 mg ALB/18 mg IVM	10000	

ELIGIBILITY CRITERIA

List inclusion criteria	List exclusion criteria	Age Category	Minimum age	Maximum age	Gender
- Age: 5 to 17 years old (included). - Height: over 90cm. - Parental acceptance to participate in the study by obtaining written informed consent approved by the Ethics Committee. Written assent will also be obtained from children according to the local national legislation. (In Kenya written assent will be obtained from children 12-17 years old and in Ghana for children 15-17 years old.)	- Epidemiological risk of being infected by Loa loa. - Serious medical illness, per investigator's criteria. - Any condition prevents the appropriate evaluation and follow-up of the participant, per the investigator's criteria. - Known hypersensitivity to any component of either study treatment. - Pregnant or first week post-partum, reported by the participant during interview.	Adolescent: 13 Year-18 Year,Child: 6 Year-12 Year,Preschool Child: 2 Year-5 Year	5 Year(s)	17 Year(s)	Both

ETHICS APPROVAL

Has the study received appropriate ethics committee approval	Date the study will be submitted for approval	Date of approval	Name of the ethics committee
No	01/03/2024		The Scientific and Ethics Review Unit SERU

Ethics Committee Address

Street address	City	Postal code	Country
P.O. BOX 54840 00200 OFF MBAGATHI ROAD, NAIROBI, KENYA	Nairobi	54840	Kenya

Has the study received appropriate ethics committee approval	Date the study will be submitted for approval	Date of approval	Name of the ethics committee
No	01/03/2024		Ethics And Research Management Ghana

Ethics Committee Address

Street address	City	Postal code	Country
Dodoo Lane, Behind Accra High Court Complex or Opposite Tema Station, Osu, Accra	Accra	-	Ghana

OUTCOMES

Type of outcome	Outcome	Timepoint(s) at which outcome measured
Primary Outcome	Frequency, type and severity of related AEs and SAEs for FDC and ALB	Day 0, 1, 2, 3, 4, 5, 6, 7
Secondary Outcome	Reduction in T. trichiura prevalence determined by microscopy for FDC and ALB.	Baseline, day 21, month 11

RECRUITMENT CENTRES

Name of recruitment centre	Street address	City	Postal code	Country
Kenya Medical Research Institution KEMRI	P.O. Box 54840 00200, Off Mbagathi Road, Nairobi, Kenya	Nairobi	54840	Kenya
Ghana Health Services GHS	Dodoo Lane, Behind Accra High Court Complex or Opposite Tema Station, Osu, Accra	Accra		Ghana

FUNDING SOURCES

Name of source	Street address	City	Postal code	Country
EDCTP	Anna van Saksenlaan 51 2593 HW The Hague, The Netherlands	The Hague	2593	Netherlands

SPONSORS

Sponsor level	Name	Street address	City	Postal code	Country	Nature of sponsor
Primary Sponsor	Laboratorios Liconsa SA	Manuel Pombo Angulo 28, Madrid 28050, Spain	Madrid	28050	Spain	Commercial Sector/ Industry

COLLABORATORS

Name	Street address	City	Postal code	Country
Barcelona Institute for Global Health ISGlobal	Rosello 132	Barcelona	08036	Spain
Wellcome Sanger Institute WSI	Hinxton, Cambridge, CB10 1SA, UK	Cambridge		United Kingdom

CONTACT PEOPLE

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Role	**Name**	**Email**	**Phone**	**Street address**
Principal Investigator	Benson Singa	singabo2008@gmail.com	254722205901	P.O. Box 54840 00200 Off Raila Odinga Way. Nairobi, Kenya.
City	**Postal code**	**Country**	**Position/Affiliation**	

Nairobi	54840	Kenya	Principal Investigator KEMRI	
Role	**Name**	**Email**	**Phone**	**Street address**
Principal Investigator	Abraham Oduro	abraham.oduro@ghs.gov.gh	233302682709	Dodoo Lane, Osu, Accra
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Accra		Ghana	Principal Investigator GHS	
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Public Enquiries	Celia Olmos	Celia.Olmos@chemogroup.com	34917711500	Laboratorios Liconsa SA, Manuel Pombo Angulo 28, Madrid 28050, Spain
City	**Postal code**	**Country**	**Position/Affiliation**	
Madrid	28050	Spain	Project Manager Laboratorios Liconsa	

REPORTING

Share IPD	**Description**	**Additional Document Types**	**Sharing Time Frame**	**Key Access Criteria**
Yes	We will share anonymized Individual Participant Data upon request through the Infectious Diseases Data Observatory (IDDO). IDDO is a scientifically independent, multi-disciplinary coalition of the global infectious disease and emerging infections communities. It provides the methods, governance and infrastructure to translate data into evidence that improves outcomes for patients worldwide.	Statistical Analysis Plan,Study Protocol	-	-
URL	**Results Available**	**Results Summary**	**Result Posting Date**	**First Journal Publication Date**
-	No			
Result Upload 1:	**Result Upload 2:**	**Result Upload 3:**	**Result Upload 4:**	**Result Upload 5:**
Result URL Hyperlinks	**Link To Protocol**			
Result URL Hyperlinks				

Changes to trial information