

Evaluation of the diagnostic performance of a mobile digital technology for the detection and quantification of soil-transmitted parasites among school children in Kenya

Submission date 15/07/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/07/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/04/2022	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Soil-transmitted helminths (STH), including hookworm, roundworm and whipworms, are common intestinal infections in Kenya. Global estimates indicate that more than 1.4 billion people are infected with at least one STH species. They cause anaemia, gastro-intestinal problems, tiredness amongst other symptoms. The most affected and at-risk populations are school children and these infections impede their physical growth and cognitive development, contributing significantly to school absenteeism. The current control strategy recommended by the World Health Organization (WHO) is yearly treatment of children with a single-dose treatment of albendazole. However, after treatment, reinfection can occur if the environment remains contaminated with infective eggs/larvae. In this research, we want to learn more about new ways to detect eggs/larvae in stool.

Who can participate?

Children attending classes 1-6 who are aged 5-15 years will be randomly selected to participate. In total we will recruit 1,354 school children.

What does the study involve?

We will take a small stool sample from the study participants to find out whether they are infected with worms or not. We will also provide a questionnaire to learn about the households of the participants, deworming medication used and the availability and use of safe water and sanitation. We will also map participant's houses in order to help locate the household during follow-up visits.

What are the possible benefits and risks of participating?

All infected individuals will receive deworming treatment recommended by the ministry of Health. Participants may be uncomfortable providing stool samples for worm screening.

Where is the study run from?
Kenya Medical Research Institute

When is the study starting and how long is it expected to run for?
May 2020 to April 2021

Who is funding the study?
European Union Horizon 2020

Who is the main contact?
Dr. Stella Kepha, stellakepha2005@yahoo.com

Study website
<https://www.spotlab.org/>

Contact information

Type(s)
Public

Contact name
Dr Stella Kepha

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SERU/4002

Study information

Scientific Title

Evaluation of the diagnostic performance of a mobile digital technology for the detection and quantification of soil-transmitted helminths among school children in Kenya

Study objectives

The diagnostic performance of a modified version of KK technique which entails; visualization of the sample through (1) a mobile phone coupled to the ocular of the microscope and (2) a web-based telemicroscopy platform is as sensitive as conventional visual analysis using only optical microscopy, as it is done in conventional KK technique

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 26/05/2020, Kenya Medical Research Institute, Scientific and Ethics Committee (P.O. Box 54840-00200, Nairobi, Kenya; +254 2722541; erc@kemri.org), ref: KEMRI/RESR/7/3/1

Study design

Observational cross-sectional study

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

School

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Helminth infection

Interventions

This study will be a school-based cross-sectional survey among school children (5-15 y) conducted to determine the prevalence of STH among this age group. This study will be conducted over 1 y.

In each school eligible children with signed informed consent [class/grade 1-6, age (5-15 y)] will be randomly selected and tested for the presence of STH.

To determine the performance of the SpotLab technology in assessing the treatment efficacy of albendazole, 250 STH positive children will provide 2 consecutive days stool sample before and 21 days after treatment.

Intervention Type

Other

Primary outcome measure

Prevalence of soil transmitted infection based on the detection of STH eggs on a slide by using the Kato-Katz thick smear method at baseline and 21 days

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

26/05/2020

Completion date

30/04/2021

Eligibility

Key inclusion criteria

1. Permanent resident of community (≥ 6 months)
2. School children aged 5-15 years
3. Provision of informed consent or informed consent from parent or legal guardian
4. Provision of assent by individuals (12-15)

Participant type(s)

Healthy volunteer

Age group

Child

Lower age limit

5 Years

Upper age limit

15 Years

Sex

Both

Target number of participants

1,354

Total final enrolment

1343

Key exclusion criteria

Individuals unwilling to participate in the study

Date of first enrolment

01/09/2020

Date of final enrolment

04/04/2021

Locations

Countries of recruitment

Kenya

Study participating centre**Kenya Medical Research Institute**

Mbagathi Road

P.O. Box 54840

Kwale town

Nairobi

Kenya

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Sponsor information

Organisation

Kenya Medical Research Institute

Sponsor details

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Sponsor type

Research organisation

Website

<http://kemri.org>

ROR

<https://ror.org/04r1cxt79>

Funder(s)

Funder type

Government

Funder Name

European Union's Horizon 2020 programme

Results and Publications

Publication and dissemination plan

The results will be presented at appropriate national and international scientific meetings and papers will be written and submitted to peer-reviewed scientific journals for publication.

Intention to publish date

01/08/2020

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		19/04/2022	19/04/2022	No	No
Other publications	Training of AI system	07/09/2021	19/04/2022	Yes	No