ISRCTN11195538 https://doi.org/10.1186/ISRCTN11195538

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

Registration date
22/07/2020

Overall study status
Completed

Last Edited
19/04/2022

Condition category
Infections and Infestations

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

Organisation
Kenya Medical Research Institute

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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