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Investigating whether a new test can be used to differentiate between viruses, malaria and bacteria as causes of fever among children in Ghana

Submission date
06/03/2024

Recruitment status
No longer recruiting

Registration date
25/04/2024

Overall study status
Ongoing

Last Edited
07/04/2026

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study will evaluate a new test for the cause of fever in African children. There is an unmet need for diagnostic tests that can be used in African countries where resources are scarce. Most of the time, when children have a fever, the only test available is a malaria test. If this test is negative, they often receive antibiotic treatment because tests to distinguish between other causes of infection (e.g., bacteria or viruses) are unavailable. The aim of this study is to use how the human immune system responds to infection to tell which type of infection someone has. The researchers will detect genes that are turned on and off in the blood which are specific to either bacterial, viral, or malaria infection.

Who can participate?
Children between the ages of 1 month and 15 years presenting to the recruiting facilities with fever

What does the study involve?
The study will record participant data, some of which include the clinician's notes on the signs /symptoms, medications, and preexisting conditions, and demographic information such as age, sex, location, and ethnicity. In addition to this, the researchers will request the results of laboratory tests run for routine healthcare. They will also take about a spoonful of blood for laboratory testing for the study.

What are the possible benefits and risks of participating?
There are no direct benefits to taking part in this study. However, it is hoped that the information gained from this study may someday make it easier and faster for doctors to diagnose individuals infected with germs that cause illness and fever. This study will benefit the scientific community by providing information for future use in the evaluation of this new test. There is minimal risk associated with the collection of a blood specimen. The participant may experience some mild pain, discomfort, and/or bruising. These risks are no greater for this study

than for routine testing from blood samples. Well-trained laboratory personnel will perform this according to standard guidelines to minimize the possible risks.

Where is the study run from?
The West Africa Centre for Cell Biology of Infectious Pathogens at the University of Ghana (Ghana)

When is the study starting and how long is it expected to run for?
August 2022 to December 2026

Who is funding the study?
The study is funded by the NIHR (NIHR-Global Health Research Group's Digital Diagnostics for African Health Systems, project reference NIHR134694) using UK International Development funding from the UK Government to support global health research. The views expressed are those of the authors and not necessarily those of the NIHR or the UK government.

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

National Institute for Health and Care Research (NIHR)
NIHR134694

Study information

Scientific Title
Evaluating the potential of a Lacewing host-response assay to distinguish between malaria, bacterial and viral infection as causes of acute childhood febrile illness in The Gambia and Ghana

Acronym
LacewingAFI

Study objectives
The measurement of the expression of a small number of genes in blood using a point-of-care molecular diagnostic test can be used to distinguish between viruses, bacteria and malaria infections

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 09/10/2023, Ghana Health Service Ethics Review Committee (Research and Development Division, Ghana Health Service, Accra, MB190, Ghana; +233 (0)302681109; ethics.research@ghs.gov.gh), ref: GHS-ERC: 017/06/23

2. approved 29/06/2023, Ethics Committee for Basic and Applied Sciences (Ethics Committee for Basic and Applied Sciences, University of Ghana, Accra, LG1195, Ghana; +233 (0)302213820; ethicscbas@ug.edu.gh), ref: ECBAS 038/ 22-23

Study design
Multicenter cross-sectional study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Diagnosis of malarial, viral and bacterial infections among children with fever

Interventions
Clinical samples will be obtained from participants recruited from the hospitals and stored samples from previous ethically approved studies. These will be tested for host signature transcripts using a benchtop reverse transcription loop-mediated isothermal amplification (RT-LAMP) assay and the Lacewing device. The diagnostic performance, sensitivity and specificity of the device will be assessed by comparing results with gold standards such as microscopy, bacterial cultures, and molecular diagnostics (for example TaqMan array card).

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Lacewing

Primary outcome(s)
Diagnostic accuracy will be measured using the area under the receiver operator curve (AUC) for the results of the Lacewing device compared against reference standard (blood film microscopy, sterile site culture, and molecular pathogen detection), assessed at the time of clinical presentation.

Key secondary outcome(s))
1. The prevalence of different types of infection classified by gene expression test will be assessed for samples collected at time of clinical presentation
2. The usability of the test will be evaluated through stakeholder engagements on the day that the primary outcome is measured

Completion date
31/12/2026

Eligibility

Key inclusion criteria

1. The participant is between the ages of 1 month and 15 years
2. Participant has a reported fever or recorded fever of ≥37.5°C in the past 24 hours and is suspected by a clinician to have an infection
3. Parental permission and child assent have been obtained

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
1 months

Upper age limit
15 years

Sex
All

Total final enrolment
353

Key exclusion criteria
1. Children aged 16 years or older
2. Children without recorded/reported fever.
3. Inability to provide informed consent.
4. Children with fever from a suspected hospital-acquired infection
5. Children suspected by clinicians to have a high-consequence infectious disease such as viral haemorrhagic fever
6. Children with known HIV or other immunodeficiency

Date of first enrolment
15/03/2024

Date of final enrolment
28/03/2025

Locations

Countries of recruitment
Ghana

Study participating centre

Ledzokuku-Krowor Municipal Hospital
Ghana Health Service
Teshie-Tsuibleoo
Accra
Ghana
GZ-103-2962

Study participating centre
Oda Government Hospital
Ghana Health Service
Akyem-Oda
Oda
Ghana
P O Box 16

Study participating centre
Kintampo Municipal Hospital
Ghana Health Service
Kintampo
Ghana
PO Box 192

Study participating centre
War Memorial Hospital
Ghana Health Service
Navrongo
Ghana
PO Box 34

Sponsor information

Organisation
University of Ghana

ROR
https://ror.org/01r22mr83

Funder(s)

Funder type

Government

Funder Name
NIHR Global Health Research Group on Digital Diagnostics for Africa

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Prof. Aubrey Cunnington (a.cunnington@imperial.ac.uk) or Dr. Samuel Duodu (Sa.duodu@ug.edu.gh)

IPD sharing plan summary
Available on request