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Evaluating a novel diagnostic test for the detection of Plasmodium infections at community level in The Gambia and Burkina Faso

Submission date
18/07/2024

Recruitment status
No longer recruiting

Registration date
15/08/2024

Overall study status
Ongoing

Last Edited
16/12/2025

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
To advance the goal of malaria elimination, targeting the entire human malaria reservoir, encompassing both symptomatic and asymptomatic infections is imperative. Active detection interventions, involving community-level testing and treatment approaches, could contribute to achieving this objective. A key prerequisite for the success of such interventions is the availability of highly sensitive and field-deployable diagnostic tests capable of detecting all infections, including those of low parasite density in asymptomatic carriers. Conventional diagnostic tests such as Rapid Diagnostic Tests (RDT), microscopy, and Polymerase Chain Reaction (PCR) currently fall short of meeting these criteria. A novel molecular-based test, Dragonfly, exhibit the potential to address the challenge of detecting low parasite-density infections. The study aims to evaluate the diagnostic accuracy of Dragonfly in detecting Plasmodium infection at community level.

Who can participate?
Individuals aged 6 months and above residing in the two study sites

What does the study involve?
Once consent has been obtained, a questionnaire will be introduced to each participant to collect socio-demographic data such as age, sex; preventive measures against malaria that the person is using; symptoms presented by the participant at the time of the interview. A few drops of blood will then be taken from the participant's finger to perform the malaria tests.

What are the possible benefits and risks of participating?
As a direct benefit, all participants will receive malaria screening using RDTs validated by the National Malaria Control Program. Those who test positive will be treated according to the National Malaria Control Program guidelines. Moreover, it is hoped that the information gained from this study will be used to guide the fight against malaria in the two countries and beyond. There is minimal risk associated with the collection of a blood specimen. The participant may

experience pain, discomfort when pricked on the finger. Samples will be taken by trained health professionals using sterile and single-use equipment.

Where is the study run from?
MRC Unit The Gambia at LSHTM, Banjul Fajara (The Gambia)
Clinical Research Unit of Nanoro, Nanoro Department (Burkina Faso)

When is the study starting and how long is it expected to run for?
June 2022 to June 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.

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
29611

Study information

Scientific Title
Evaluating a novel diagnostic test for the detection of Plasmodium infections at community level in The Gambia and Burkina Faso

Acronym
DIDA-SP1

Study objectives
The novel diagnostic test, Dragonfly, a novel LAMP-based technology, can accurately detect Plasmodium infections, including asymptomatic carriers characterized by low parasite densities

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 17/11/2023, London School of Hygiene and Tropical Medicine Ethics Committee (Keppel Street, London, WC1E 7HT, United Kingdom; +44 (0)20 7636 8636; ethics@lshtm.ac.uk), ref: 29611 1

2. approved 06/11/2023, The Gambia Government/MRC Joint Ethics Committee (MRC unit The Gambia at LSHTM, Banjul, 273, Gambia; +220 4495919; ethics@mrc.gm), ref: 29611

3. approved 06/03/2024, Comite d'Ethique pour la Recherche en Sante- Ministere de la Sante et de l'Hygiene Publique Burkina Faso (Ministère de la Santé Building Lamizana, Ouagadougou, -, Burkina Faso; -; noEmail@ddressProvided), ref: 2024-03-61

Study design
Multicenter cross-sectional study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Diagnosis of Plasmodium infection

Interventions
Clinical samples will be obtained from participants recruited through community-based cross-sectional surveys. These samples will be tested for Plasmodium infection using Dragonfly, RDT, microscopy, and PCR. The diagnostic performance of the novel test will be assessed by comparing its results with those obtained from PCR.

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome(s)
Diagnostic accuracy of Dragonfly in detecting Plasmodium infection at the time of recruitment assessed by comparing Dragonfly results against reference standard (PCR).

Key secondary outcome(s))
1. Diagnostic accuracy of RDT in detecting Plasmodium infection at the time of recruitment by comparing RDT results against reference standard (PCR).
2. Diagnostic accuracy of microscopy in detecting Plasmodium infection at the time of recruitment by comparing microscopy results against reference standard (PCR).
3. Ease of use of Dragonfly assessed using qualitative interview guides within 4 weeks after presentation of Dragonfly technology to the potential users.
4. Factors influencing the uptake of community-based interventions such as mass testing and treatment assessed using qualitative interview guides within 6 months after the cross-sectional surveys.

Completion date
20/06/2026

Eligibility

Key inclusion criteria
1. >6 months of age
2. Present in the household at the time of the interviews
3. Consent to participate in the study (or consent given by an adult caregiver if <18 years old and assent for children ≥12 years old)

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
6 months

Upper age limit
99 years

Sex
All

Total final enrolment
1274

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
09/11/2023

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Burkina Faso

Gambia

Study participating centre
MRC Unit The Gambia at LSHTM
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Study participating centre
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Clinical Research Unit Nanoro
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Sponsor information

Organisation
MRC Unit The Gambia at LSHTM

Organisation
Clinical Research Unit Nanoro

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. Umberto D'Alessandro (umberto.dalessandro@lshtm.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes