

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 Recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 15/08/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 15/08/2024	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Cross sectional study

Study setting(s)

Community

Study type(s)

Diagnostic

Participant information sheet

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

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

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Dragonfly

Primary outcome measure

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

Secondary outcome measures

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.

Overall study start date

01/06/2022

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

Age group

All

Lower age limit

6 Months

Sex

Both

Target number of participants

1900

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

Atlantic Boulevard, Fajara

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Study participating centre

Clinical Research Unit Nanoro

Clinical Research Unit Nanoro

Nanoro Department

Burkina Faso

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Sponsor type

Research council

Website

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Research organisation

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Funder(s)**Funder type**

Government

Funder Name

NIHR Global Health Research Group on Digital Diagnostics for Africa

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

20/06/2027

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