

Evaluation of a new and simple diagnostic test for malaria

Submission date 19/01/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 22/02/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/10/2023	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Malaria is the most important parasitic disease worldwide. The disease is caused by the malaria parasite which dwells in the blood of infected patients. It is important to find out if a case is infected as immediate treatment with the right drugs is important to circumvent death or severe disease. Current tests (diagnostic tests, like microscopy or rapid diagnostic tests) to detect the malaria parasite in blood have limitations. They may not be sensitive enough (do not detect the parasite; they are "false negative") or remain positive after successful treatment ("false positive"). A molecular diagnostic test based on the detection of parasite genetic material (DNA) might be much better, but their use in resource-limited countries (like many countries in Africa), because they require sophisticated equipment and a constant supply of electricity.

Our project has developed a simple molecular diagnostic test that circumvents difficult DNA extractions (it is directly on blood), requires simple equipment (mini PCR machine), runs on solar power, and has a simple dipstick readout system. In the current project, we want to explore how well these new tests can detect malaria parasites in blood compared to currently available systems. The work is done in 5 African countries (Sudan, Ethiopia, Burkina Faso, Kenya, and Namibia) that all face problems with malaria diagnosis.

Who can participate?

Persons living in the catchment areas of the health centres of the participating study institutes with the suspicion of malaria (male/female, all ages) can participate in the study.

What does the study involve?

Persons who participate in the study are suspected of having malaria and attend a health facility. In addition to blood samples that will be taken from them in the context of routine diagnosis, we will take an additional small blood sample for experimental testing. Furthermore, we will take some additional clinical and demographic data. The outcome of experimental testing will not be used for the clinical management of study cases. The patients will be treated and managed according to the national health guidelines for malaria.

What are the possible benefits and risks of participating?

Cases will not have to pay the service fee for their clinic visit during this study. This study will

help us to learn how the new diagnostic test will work best in patients. This may help to provide (potential) malaria patients with a better diagnosis in the future.

The risks to the safety of participants in the study is negligible as we will not provide any experimental drug. In addition, our new test will not influence the care the doctor will provide to cases and treatment will be based on the results of the health facility's usual tests. The only risk we see could be that related to the blood collection. Indeed, the risks of drawing blood from a finger prick include temporary discomfort from the needle stick, bruising, skin infection, and fainting. However, the amount of blood collected is too small to affect participants", and any discomfort will rapidly go away.

Where is the study run from?

Academic Medical Center (Netherlands)

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

March 2019 to November 2024

Who is funding the study?

European and Developing Countries Clinical Trials Partnership

Who is the main contact?

Dr Henk Schallig, h.d.schallig@amsterdamumc.nl

Study website

<https://www.malariadx.org>

Contact information

Type(s)

Principal Investigator

Contact name

Dr Henk Schallig

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

PACTR202202766889963

Study information

Scientific Title

Phase 3 evaluation of an innovative simple molecular test for the diagnosis of malaria in different endemic and health settings in sub-Saharan Africa

Acronym

DIAGMAL

Study objectives

The diagnostic performance of the mini-dbPCR-NALFIA test for malaria (investigational product) has a better diagnostic performance than current diagnostic practises in place in the participating study sites

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 07/04/2021, Ethics committee of the University of Gezira, Faculty of Medicine (P.O. Box 20 Wad Medani, Sudan; +249912320250; saeedosman82@yahoo.com), ref: n/a
2. Approved 10/03/2021, National ethical committee for research (03 BP7009 Ouagadougou, Burkina Faso; +226 25 33 35 94; kouetafla@yahoo.com), ref: 2021-03-057
3. Approved 01/04/2021, Institutional ethical committee in health sciences (Comité d'Ethique Institutionnel pour la Recherche en Science de la Santé, Centre National de la Recherche Scientifique et Technologique, Direction Régionale Ouest, 01 BP 545 Bobo-Dioulasso 01, Burkina Faso; +226 20981880; rouama_noelw@yahoo.fr), ref: N/Réf. A02-2021/CEIRES
4. Approved 30/06/2021, Department research ethics review committee (DRERC) of the department of microbiology, Immunology and Parasitology (DMIP) (Addis Ababa University, Addis Ababa, Ethiopia; no telephone number provided; abelishasweet@yahoo.com), ref: DRDRC /04/2021
5. Approved 25/11/2021, Ministry of Education (National Ethics Review Committee; Ministry of Education, Addis Ababa, Ethiopia; no telephone number provided; daniel.tadesse@ethernet.edu.et), ref: 7/1-61/m259/35
6. Approved 07/09/2021, Institutional Review Board of the Addis Ababa University, College of Health Science (Addis Ababa, Ethiopia; no telephone number provided; adamuaddissie@gmail.com), ref: 07/2021
7. Approved 01/07/2021, Amref Ethics and Scientific Review Committee (P.O. Box 30125, 00100 Nairobi, Kenya; +254.20.6994000; esrc.kenya@amref.org), ref: AMREF – ESRC P991/2021
8. Approved 12/04/2021, Ministry of Health and Social Services (Harvey Street Private Bag, 13198 Windhoek, Namibia; +264.61.203.2507; Shipanga@mhss.gov.na), ref: 17/3/3/DRM

Study design

Phase 3 diagnostic trial

Primary study design

Observational

Secondary study design

Phase 3 diagnostic trial

Study setting(s)

Other

Study type(s)

Diagnostic

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Malaria (uncomplicated Plasmodium falciparum malaria)

Interventions

Comparison of different diagnostic tests for malaria.

Diagnostic performance will be assessed following the WHO/TDR guidelines for the evaluation of diagnostics and the results will be reported according to STARD principles. This phase 3 evaluation will be a prospective multi-centre diagnostic study on populations living in different malaria endemic settings and for which the disease status of each individual is not previously known. Study participants (all ages) will be identified during their visits at the study health facilities. Subjects (or parent or legal guardian in case of minors) suspected of having malaria will be asked to participate in the diagnostic study.

Next to a blood sample collected for routine diagnosis in place for malaria, from each eligible case a blood sample (finger prick) will be collected in an sample (EDTA) tube for analysis with the test under investigation. An additional sample will be collected on filter paper for further comparison and quality control with PCR in reference laboratory. Some basic clinical and demographic data will be collected too. After sample collection the patients will be further referred to the local clinical practise in place. The result of experimental testing will not be taken into account whilst managing the patient. There will be no active follow-up of cases. The total duration of participation is estimated to be between 10 and 60 minutes.

Intervention Type

Device

Phase

Phase III

Drug/device/biological/vaccine name(s)

Not applicable

Primary outcome measure

Diagnostic accuracy measured as sensitivity, specificity, negative and positive predictive value of index test (dbPCR-NALFIA) compared to reference (standard) tests at point of diagnostic testing (enrolment of study case)

Secondary outcome measures

1. To determine the direct and indirect costs and benefits of allocating limited resources to implement the mini-dbPCR-NALFIA test for malaria compared to current diagnostic strategies in place. Descriptive outcome measured as availability of a report at the end of the trial
2. To determine potential barriers to successfully implement the new diagnostic platform within local, socio-economic and cultural contexts under routine conditions. Descriptive outcome measured as availability of a report at the end of the trial
3. To build a draft product dossier for CE marking and pre-qualification and to identify potential producers that can bring the platform to the market (exploitation objective). Effectiveness of dossier drafting is measured by the availability of a draft product dossier at the end of the trial
4. To strengthen the capacity of all five African partners in the field of diagnostic clinical trials, including Good Clinical and Laboratory Practices (GC/LP) training of research and auxiliary staff and prospective MSc/ PhD students, and to improve the research infrastructure at the trial sites. Effectiveness of capacity building is measured as number of staff trained at the end of the trial.
5. To disseminate the outcomes of the project to stakeholders, including scientific peers, diagnostic entities, policy makers and the lay public. Effectiveness of dissemination is measured as number of publications in peer reviewed journals at the end of the trial

Overall study start date

19/03/2019

Completion date

30/11/2024

Eligibility

Key inclusion criteria

In Sudan, Ethiopia, Burkina Faso and Kenya, the study will include patients who fulfil the following inclusion criteria:

1. Potential participant (patients with clinical suspicion of malaria) of all ages presenting at the health facility;
2. Coming from the health centre catchment area;
3. Informed consent from patient or of parents/guardians (in case of minors).

In Namibia, the study will include persons who fulfil the following criteria:

1. Be a resident of one of the selected households or have slept the night before in this household.
2. Informed consent from potential participants (individually).

Participant type(s)

Other

Age group

All

Sex

Both

Target number of participants

-Sudan (10% incidence): 876 study cases; -Ethiopia (10% incidence): 876 study cases; -Burkina Faso (20% incidence): 438 study cases; - Kenya (25% incidence): 351 study cases; - Namibia: prevalence is <1.5% in the near elimination study region. Therefore, we will perform a cross sectional study targeting 2,000 people in the study areas as was also done in a previous study

Total final enrolment

4541

Key exclusion criteria

Not meeting the above inclusion criteria, depending on study site.

Date of first enrolment

01/12/2021

Date of final enrolment

31/05/2024

Locations**Countries of recruitment**

Burkina Faso

Ethiopia

Kenya

Namibia

Sudan

Study participating centre

Institut de Recherche en Sciences de la Santé (IRSS)

Clinical Research Unit of Nanoro (CRUN)

Nanoro

Burkina Faso

BP 218 Ouaga CMS 11

Study participating centre

Blue Nile National Institute for Communicable Diseases

University of Gezira

Wad Medani

Sudan

01

Study participating centre
Amref Health Africa Headquarters
Wilson Airport
Nairobi
Kenya
01

Study participating centre
Addis Ababa University
Department of Microbiology, Immunology and Parasitology, College of Health Sciences,
Addis Ababa
Ethiopia
01

Study participating centre
University of Namibia
Multidisciplinary Research Center
Windhoek
Namibia
01

Sponsor information

Organisation
Academic Medical Center

Sponsor details
Meibergdreef 9
Amsterdam
Netherlands
1105AZ
+31.20.5665454
p.f.mens@amsterdamumc.nl

Sponsor type
Hospital/treatment centre

Website
<https://www.amc.nl>

ROR
<https://ror.org/03t4gr691>

Funder(s)

Funder type

Government

Funder Name

European and Developing Countries Clinical Trials Partnership

Alternative Name(s)

Le partenariat Europe-Pays en développement pour les essais cliniques, A Parceria entre a Europa e os Países em Desenvolvimento para a Realização de Ensaios Clínicos, The European & Developing Countries Clinical Trials Partnership, European and Developing Countries Clinical Trials, EDCTP

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

Netherlands

Results and Publications

Publication and dissemination plan

Results will be published in a peer reviewed journal (preferably Open Access) after completion of the trial and data analysis

Intention to publish date

01/11/2025

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/09/2022	02/09/2022	Yes	No