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Tafenoquine feasibility study in Ethiopia

Submission date 06/06/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 12/03/2024	**Overall study status** Completed	
Last Edited 08/01/2026	**Condition category** Infections and Infestations	

Plain English summary of protocol

Background and study aims
Malaria is a major health problem in many countries of the world and in Ethiopia malaria is a significant health problem and one of the leading causes of illness and death. In 2020 over 15 million suspected and over 1.7 million cases were reported. This study assesses a new way of treating P. vivax malaria. This method involves a new drug, called tafenoquine, which can only be given to people who do not have a hereditary condition called G6PD deficiency. The main goal of this study is to see if this new approach works well in practice, and secondly to check if it is safely implemented, acceptable and cost-effective. The study will roll out this updated treatment plan in health facilities across two regions and test it. In this study, how well G6PD testing and TQ work in the current treatment system and how much that cost will be assessed. The evidence collected will be used to inform future decisions. The study will use a mix of methods, including looking at the numbers from case management records, talking to people through interviews and group discussions, and collecting cost information.

Who can participate?
Patients aged 6 months onward and eligible as per revised treatment guidelines with a confirmed diagnosis of P. vivax infections and willing to participate in the study. Additionally, the study will include healthcare providers directly or indirectly involved in the management of P. vivax malaria patients. For a sub-study focusing on assessing malaria testing instruments, patients who are suspected of having malaria will also be included in the study.

What does the study involve?
Patients will be provided with a radical cure treatment following the G6PD test and will be followed up. Adherence of the healthcare providers to the revised treatment algorithm will be primarily assessed. In addition, in two sub-studies the outcome of using TQ and improved rapid diagnostic tests for malaria detection will be measured.

What are the possible benefits and risks of participating?
There is no direct benefit for the participants, but they will contribute to improving the quality of care for vivax patients in Ethiopia and help to eliminate vivax malaria from the community. There are no expected risks but the study will pay for any care needed and no cost will be incurred for the participant.

Where is the study run from?
The study will run in two regions in Ethiopia called South Ethiopia and Gambela

When is the study starting and how long is it expected to run for?
January 2020 to November 2025

Who is funding the study?
Unitaid (Switzerland)

Who is the main contact?
Dr Endalamaw Gadisa, endalamaw.gadisa@ahri.gov.et

Contact information

Type(s)
Principal investigator

Contact name
Dr Endalamaw Gadisa

Contact details
Armauer Hansen Research Institute
Addis Ababa
Ethiopia
PO Box 1005
+251 (0)113483752
endalamaw.gadisa@ahri.gov.et

Additional identifiers

Protocol serial number
PO 59-22

Study information

Scientific Title
Operational feasibility of appropriate radical cure of plasmodium vivax with tafenoquine or primaquine after semi-quantitative G6PD testing in Ethiopia

Acronym
TQET

Study objectives
It is operationally feasible to provide radical cure (RC) treatment semi-quantitative after glucose-6-phosphate dehydrogenase (G6PD) testing to P. vivax patients who are eligible for RC and patients will receive the correct treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/02/2023, National Research Ethics and Review Board (NRERB, PO Box 1367, Arada sub city, Addis Ababa, Ethiopia; +251 (0)11 155 3133; info@moe.gov.et), ref: 17/256/695/23

Primary study design
Interventional

Study design
Multicenter international prospective longitudinal study and sub-studies: a prospective cross-sectional study

Study type(s)
Diagnostic, Treatment

Health condition(s) or problem(s) studied
P. vivax malaria

Interventions
The main intervention will be a revised treatment algorithm for vivax malaria integrating tafenoquine and G6PD test before radical cure treatment of vivax malaria. Tafenoquine (TQ) 300 mg will be administered as a single dose co-administered on the first or second day of chloroquine therapy. Supportive interventions include training of healthcare providers and strengthening of pharmacovigilance and patient follow-ups. There will be a patient follow-up visit on Days 3, 7, and 13 (-1 day; +2 days) after treatment for all patients who received radical cure treatment. Patients will be evaluated for early signs of AHA during follow-up visits. In a subset of two facilities, two ancillary sub-studies will be conducted with participants co-enrolled in the main study.

Intervention Type
Other

Primary outcome(s)
Measured using patient records at the end of the study:
1. Proportion of vivax patients that are correctly treated with RC based on the revised algorithm based on patient records during the study period
2. Proportion of HCPs that adhere to the revised RC algorithm as relevant to their role in the health system based on patient records during the study period

Key secondary outcome(s)
Measured using patient records at the end of the study:
1. Proportion of non-eligible patients that receive Radical Cure (TQ&PQ) treatment
2. Proportion of patients experiencing acute haemolytic anaemia (AHA) during the follow-up period, proportion of all AHA identified by HCPs and total number of AHAs identified during the study
3. The extent to which health facilities have consistent process to evaluate pregnancy status and functioning referral system in place, including emergency transportation and access to blood transfusion in referral facilities, assessed from routine monitoring visit reports
4. Proportion of HCPs who are able to correctly identify 8AQ-related adverse events
5. Healthcare provider satisfaction with the training provided assessed through training evaluation questionnaire and qualitative methods; knowledge and skills regarding G6PD testing and radical cure treatment over time, as determined by a competency assessment

6. Number and frequency of supervisory visits conducted during the study duration per health facility, adherence to supervision Standard Operating Procedure (SOP), and proportion of HCP who received personal routine supervision in the past 6 months, assessed from health facilities routine monitoring visit reports and qualitative methods
7. Patients and health care provider perceptions of and experience with the new RC tools, as reported in interviews and focus group discussions
8. Total monetary cost of G6PD testing, tafenoquine, training sessions and G6PD diagnostic quality assurance
9. Per patient monetary cost of including G6PD testing and single-dose cure from the perspective of the health system
10. The total number of additional malaria infections reported by study participants who receive TQ during the follow-up period
11. The number of study participants who received TQ and presented again to the facility with an additional malaria infection during the follow-up period
12. The total number of malaria infections that are identified by the BIOCREDIT but are not detected through microscopy
13. The overall proportion of malaria infections that are identified by the BIOCREDIT, as calculated by the ratio between infections detected by BIOCREDIT over infections detected by PCR

Completion date
06/11/2025

Eligibility

Key inclusion criteria
1. Patient with a confirmed P. vivax infection
2. Patients providing informed consent or assent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
6 Months

Upper age limit
100 Years

Sex
All

Total final enrolment
3726

Key exclusion criteria
1. Unwilling to provide informed consent
2. Showing signs of severe infection (patients)

Date of first enrolment
04/11/2024

Date of final enrolment
03/11/2025

Locations

Countries of recruitment
Ethiopia

Study participating centre
Health facilities
SNNPR and Gambella
Ethiopia
493 code 1110

Sponsor information

Organisation
PATH

Funder(s)

Funder type
Research organisation

Funder Name
Unitaid, Global Health Campus

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date