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Tafenoquine feasibility study in Vietnam

Submission date
27/11/2023

Recruitment status
No longer recruiting

Registration date
07/12/2023

Overall study status
Completed

Last Edited
25/03/2026

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
Malaria is a big health issue in many countries around the world. Among the six types of parasites causing malaria in humans, Plasmodium vivax (P. vivax) is the second most common after P. falciparum, and it's found in the widest range of places. According to the World Health Organization (WHO), there were about 6.4 million cases of P. vivax malaria globally in 2019. P. vivax infection is marked by the persistence of dormant parasites (called liver-stage hypnozoites), leading to recurring malaria episodes months or even years after the first infection.

This study is looking into the practicality of a new way of treating P. vivax malaria. The main goal is to see if this new approach works well in practice, and the secondary goals are to check if it's safe, acceptable, and cost-effective. The new treatment plan includes using a quick test for G6PD and a radical cure treatment with tafenoquine (TQ). The study will roll out this updated plan in health facilities across six districts and also test it in different strategies for finding cases: actively looking for cases, reacting when cases are found, and just waiting for people to come in for treatment. The study will compare how well G6PD testing and TQ work in these different strategies and how much they cost. 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, talking to people through interviews and group discussions, and comparing costs between the different case-finding approaches.

To make sure the new approach is safe, the study will keep track of patients and deal with any cases of serious side effects. The people involved in the study include those with P. vivax malaria, the healthcare workers treating them, and the staff in charge of malaria programs who actively look for cases.

Who can participate?
Patient with a confirmed P. vivax infection, aged 6 months or older.

What does the study involve?
Patients will be routinely treated according to the national treatment guidelines.

What are the possible benefits and risks of participating?
None

Where is the study run from?
PATH (Switzerland)

When is the study starting and how long is it expected to run for?
June 2023 to November 2025

Who is funding the study?
Bill and Melinda Gates Foundation (USA)
Unitaid (Switzerland)

Who is the main contact?
Dr Thang Tran, thangtran@path.org
Prof Phuc Bui, phucnimpe@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Phuc Bui

Contact details
34 Trung Van street, Nam Tu Liem district
Ha Noi
Viet Nam
100000
+84 983522874
phucnimpe@gmail.com

Type(s)
Scientific

Contact name
Dr Thang Tran

Contact details
11th floor, 49 Hai Ba Trung Steet, Tran Hung Dao Ward, Hoan Kiem District
Ha Noi
Viet Nam
100000
+84 913301883
thangtran@path.org

Additional identifiers

Protocol serial number
MMV_TQ_Vietnam_2201

Study information

Scientific Title
A mixed-method operational research study on the use of tafenoquine and G6PD testing for radical cure of Plasmodium vivax malaria in passive and active case detection in Vietnam

Study objectives
The use of tafenoquine after semi-quantitative G6PD testing for radical cure of Plasmodium vivax malaria is operationally feasible based on the revised algorithm in Vietnam, a country approaching elimination.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 25/10/2023, Ethics Review Committee of National Institute of Malariology, Parasitology and Entomology (NIMPE) (34 Trung Van street, Nam Tu Liem district, Ha Noi, 100000, Viet Nam; +84 912216817; thieunq@gmail.com), ref: 407/QD-VSR

2. Approved 13/03/2024, Ethics Review Committee of World Health Organization (Avenue Appia 20 1211 Geneva Switzerland, Geneva, 1201, Switzerland; +41 22 791 21 1; evansr@unitaid.who.int), ref: ERC.0003965

Primary study design
Observational

Study design
Prospective longitudinal operational study with mixed-methods approach including qualitative component quantitative component and costing component

Study type(s)
Diagnostic, Treatment

Health condition(s) or problem(s) studied
Malaria plasmodium vivax

Interventions
Patients will be routinely treated according to the national treatment guidelines in which tafenoquine has been included, we only obtain the informed consent to collect data for assessment of correct indication.

Intervention Type
Mixed

Primary outcome(s)
Measured using patient records at the end of the study:
1. Proportion of P. vivax infected individuals that are correctly treated with TQ based on the revised algorithm as an aggregate and within each of three case finding strategies.
2. Proportion of P. vivax and mixed P. vivax infected individuals that are correctly treated with PQ based on the revised algorithm as an aggregate and within each of three case finding strategies.

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 hemolytic anemia (AHA) during the patient follow-up period
3. Health care provider knowledge and skills regarding G6PD testing and radical cure treatment over time as determined by a competency assessment
4. Patients, health care provider and supervisors' perceptions of and experience with the new RC tools, specifically TQ, as reported in interviews and focus group discussions
5. Total monetary cost of including G6PD testing and single dose cure compared across case finding strategies
6. Per patient monetary cost of including G6PD testing and single dose cure compared across case finding strategies.
7. Number of recurrences of P.vivax infection reported by study participants during study duration, in total and stratified by treatment type.
8. The number of study participants who present again to the facility or are identified through active case detection methods with a recurrence of P.vivax infection during study duration in total and stratified by treatment type.
9. Number of P. vivax patients reporting moderate, severe, and serious adverse events after TQ and PQ administration during the study conduct.
10. Frequency and severity of each moderate, severe, and serious adverse event reported after TQ and PQ administration during the study conduct.

Completion date
30/11/2025

Eligibility

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

Participant type(s)
Carer, Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
6 Months

Upper age limit
100 Years

Sex
All

Total final enrolment
21

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

Date of first enrolment
23/08/2025

Date of final enrolment
31/10/2025

Locations

Countries of recruitment
Viet Nam

Study participating centre
National Institute of Malariology, Parasitology and Entomology (NIMPE)
34 Trung Van street, Nam Tu Liem district
Ha Noi
Viet Nam
100000

Sponsor information

Organisation
PATH

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Funder Name
Unitaid

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			25/03/2026	No	No
Dataset	.csv file		25/03/2026	No	No
Other files	Informed consent form version 4.0	10/04/2025	23/03/2026	No	No
Plain English results			25/03/2026	No	Yes
Protocol file	version 4.0	10/04/2025	23/03/2026	No	No
Statistical Analysis Plan	version 1.0	09/12/2025	23/03/2026	No	No