

Tafenoquine feasibility study in Vietnam

Submission date 27/11/2023	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/12/2023	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/03/2025	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

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 December 2025

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

Who is the main contact?
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Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Study design

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

Primary study design

Observational

Secondary study design

Longitudinal study

Study setting(s)

Hospital, Medical and other records, Other

Study type(s)

Diagnostic, Treatment

Participant information sheet

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

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 measure

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.

Secondary outcome measures

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.

Overall study start date

08/06/2023

Completion date

31/12/2025

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient, Health professional, Carer

Age group

Mixed

Lower age limit

6 Months

Upper age limit

100 Years

Sex

Both

Target number of participants

150

Key exclusion criteria

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

Date of first enrolment

15/04/2025

Date of final enrolment

30/11/2025

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

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Sponsor information

Organisation

PATH

Sponsor details

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Sponsor type

Charity

Website

<https://www.path.org>

Funder(s)**Funder type**

Charity

Funder Name

Bill and Melinda Gates Foundation

Alternative Name(s)

Bill & Melinda Gates Foundation, 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

Publication and dissemination plan

The publications will be submitted to peer review journal

Intention to publish date

15/11/2025

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date