

TCTR ID : TCTR20190806004

Overall Recruitment Status : Recruiting

OTHER ID :

Retrospective registration
This protocol was registered after enrollment of the first participant.

Tracking Information

First Submitted Date : 06 August 2019
First Posted Date : 06 August 2019
Last Update Posted Date : 01 October 2019

Title

Public Title : Southeast Asia Malaria Research Center: Malaria epidemiology study in Thailand and Myanmar - A supplement Program for Malaria Elimination Strategy
Acronym : MPPT
Scientific Title : Southeast Asia Malaria Research Center: Malaria epidemiology study in Thailand and Myanmar - A supplement Program for Malaria Elimination Strategy
Sponsor ID/ IRB ID/ EC ID : TMEC 19-034
Registration Site : Thai Clinical Trials Registry
URL : <https://www.thaiclinicaltrials.org/show/TCTR20190806004>
Secondary ID : None

Ethics Review

1. Board Approval : Submitted, approved
Approval Number : MUTM 2019-044-01
Date of Approval : No Data
Board Name : Ethics Committee of the Faculty of Tropical Medicine, Mahidol University
Board Affiliation : Faculty of Tropical Medicine, Mahidol University
Board Contact : Business Phone : +66 2 3549100-4 Ext. 1349 and 16
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Sponsor

Source(s) of Monetary or Material Supports : US National Institute of Health
Study Primary Sponsor : Faculty of Tropical Medicine, Mahidol University
Responsible Party : Name/Official Title : Assoc. Prof. Jaranit Kaewkungwal
Organization : Faculty of Tropical Medicine, Mahidol University
Phone : +66 87 1001951 Ext. No Data
Email : jaranitk@biophics.org
Study Secondary Sponsor : None

Protocol Synopsis

Protocol Synopsis : The Greater Mekong Subregion (GMS) has set the strategic goal to eliminate malaria by 2030. Specifically, Thailand and Myanmar aim to be malaria-free by 2024 and 2030, respectively. Though GMS countries have strong political commitment to put intensive efforts to reach this goal, there are significant challenges requiring innovative strategies tailored to the whole region. One particular problem is that Plasmodium vivax has become the predominant species in the GMS. Malaria control histories have shown the extreme resilience of P. vivax to control measures. Mass drug administration (MDA) has played critical roles in many malaria eradication campaigns in the past. However, concerns exist with regard to its efficacy, sustainability, operational feasibility, and fear of accelerating drug resistance. Chloroquine/primaquine (CQ/PQ) remains effective and the frontline treatment for vivax malaria in the GMS despite sporadic reports of CQ-resistant P. vivax. Although mass primaquine preventive treatment (MPPT) has been successfully carried out to reduce and eliminate temperate zone P. vivax, it has not been evaluated in tropical countries. The goal of this study, which is a supplement program to the ICEMR Project supported by NIH, is to thoroughly assess effectiveness, feasibility, sustainability, acceptability and community engagement of MPPT as a strategy for malaria elimination in Thailand and Myanmar. To realize this central goal, two integrated studies are proposed, which leverage the overall infrastructure, collaboration network, and data

management plan of the current ICEMR program.

I. Observational Study: Assessing the acceptability of malaria interventions: a mixed method. This study aims to assess the acceptability and operational feasibility of implementing MPPT and enhanced vector-control interventions in malaria endemic villages as well as the readiness of the community and health providers for malaria elimination.

This study will collect information from 500 healthcare personnel and 1,500 adults in malaria endemic provinces including, but not limited to, 5 provinces/townships including Yala, Narathiwat, Tak, Ubon Ratchathani and Sisaket in Thailand; and Ban Mauk townships in Myanmar. In-depth interview and focus-group discussion will be performed to assess the acceptability, feasibility and readiness of conducting MPPT in malaria endemic communities and to assess public awareness, readiness and ability of existing healthcare facilities for malaria elimination in both countries. In addition, the study will assess the acceptability and feasibility of implementing enhanced vector-control interventions in endemic communities considering elimination.

II. Implementation Study: Cost-effectiveness of MPPT to accelerate malaria elimination in Southeast Asia. The specific objectives are to assess impact of MPPT on malaria transmission.

1. To conduct a cluster-randomized control trial to evaluate effectiveness of MPPT augmented to national standard of care to inform malaria elimination effort.

2. To conduct preparatory activities such as surveillance, community sensitization, and stakeholder engagement for potential scale-up.

We will conduct an implementation study to evaluate effectiveness, safety, and feasibility of MPPT in malaria communities in Thailand and Myanmar. A cross-over clustered-randomized controlled trial will be conducted in 6 clusters in Thailand and 4 clusters in Myanmar, with the total population of approximately 4,000 (2,000 in each country). The program impact will be monitored and evaluated at the human, vector, and parasite population levels. In the study, we will also prepare the target communities for potential large-scale MPPT implementation if the MPPT proved a success. Activities will include sensitizing and engaging with stakeholders including MOPH, provincial (township) authorities, operational units, and communities, and setting up passive surveillance in the future sites to provide baseline data to inform treatment allocation in possibility to scale up to the regional level. We will determine the cost-effectiveness of adding MPPT to routine national control activities to eliminate reservoirs of malaria.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied : Malaria

Keywords : Malaria elimination Vivax malaria Mass primaquine preventive treatment

Eligibility

Inclusion Criteria : For Observational study:

1. Both male and female
2. Age 18 years old or above

For Implementation study:

1. Both male and female
2. Age 1 year old or above

Gender : Both

Age Limit : Minimum : 1 Years Maximum : 0 N/A (No limit)

Exclusion Criteria : For Observational study:

1. Not willing to participate in the study
2. Unable to provide information either due to physical or mental conditions

For Implementation study:

Regarding participating in cohort

1. Not willing to participate in the study
2. Mental Illness and prisoners

Regarding drug administration:

1. Not willing to take primaquine
2. Pregnant and lactating women
3. For those age 7 years or older who has G6PD abnormal
4. Have history of allergy to primaquine
5. Have history of drug reaction, such as hemolysis or dark urine, after having primaquine

Accept Healthy Volunteers : Yes

Status

Overall Recruitment Status : Recruiting

Key Trial Dates	Study Start Date (First enrollment) : 17 July 2019	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 31 March 2021	Indicate Type : Anticipated
	Study Completion Date : 31 July 2021	Indicate Type : Anticipated

Design

Study Type : Interventional

Primary Purpose : Prevention

Study Phase : N/A

Intervention Model : Crossover

Number of Arms : 2

Masking : N/A

Allocation : Randomized

Control : Placebo

Study Endpoint Classification : Safety/Efficacy Study

Sample size

Planned sample size : 4000

Intervention Arm 1

Intervention name : Mass Primaquine Preventive Treatment (MPPT)

Intervention Type : Experimental

Intervention Classification : Drug

Intervention Description : A dose of 0.25-0.50 mg/kg of PQ will be administered daily for 14 days to all volunteers in Group 1 (who will receive PQ treatment in Year 1) aged 7 years and above with a normal G6PD test result. Volunteers in Group 1 will be switched and not receive any treatment in Year 2.

Intervention Arm 2

Intervention name : Control group

Intervention Type : No Intervention

Intervention Classification : No treatment

Intervention Description : Volunteers in Group 2 will not receive PQ in Year 1 but will be switched and receive PQ for 14 days in Year 2.

Outcome

Primary Outcome

1. Outcome Name : Reduction in malaria incidence

Metric / Method of measurement : a) The clinical malaria incidence rates, b) the Plasmodium prevalence rates

Time point : Year 1 = Month 1, Month 5 and Month 9; Year 2 = Month 1, Month 5 and Month 9; Passive Case Detection

2. Outcome Name : Cost estimates for MPPT implementation

Metric / Method of measurement : Costs spent for intervention and additional MPPT activities

Time point : Monthly/Real time

Secondary Outcome

1. Outcome Name : Baseline prevalence of G6PD deficiency in the study population

Metric / Method of measurement : G6PD-RDT

Time point : Prior to PQ administration for each group

2. Outcome Name : Rates of primaquine-induced hemolysis in females

Metric / Method of measurement : Hemoglobin level

Time point : Day 1, 2, 4, 6, 7 and 28 of PQ treatment

3. Outcome Name : Impact of MPPT on parasite genetic diversity and relapse rates

Metric / Method of measurement : Genotyping by deep sequencing of malaria parasites

Time point : Year 1 = Month 1, Month 5 and Month 9; Year 2 = Month 1, Month 5 and Month 9; Passive case detection

4. Outcome Name : Morbidity data

Metric / Method of measurement : Monthly morbidity data of reportable diseases from the surveillance system

Time point : 6-month prior to MPPT (PQ administration), during 1st and 2nd MPPT, 6-month after MPPT intervention

Location

Section A : Central Contact

Central Contact	First Name : Assoc. Prof. Jaranit	Middle Name :	Last Name : Kaewkungwal
	Degree : PhD	Phone : +66 87 1001951 Ext. : No Data	Email : jaranitk@biophics.org
Central Contact Backup	First Name : Jetsumon	Middle Name :	Lastname : Prachumsri
	Degree : PhD	Phone : +66 2 306 9187 Ext. : No Data	Email : jetsumon.pra@mahidol.edu

Section B Facility Information and Contact

- Site Name : Faculty of Tropical Medicine, Mahidol University

City : No Data	State/Province : Bangkok	Postal Code : 10400
Country : Thailand	Recruitment Status : Recruiting	

Facility Contact First Name : Assoc. Prof. Jaranit Middle Name : Last Name : Kaewkungwal

Degree : PhD Phone : +66 87 1001951 Ext. : No Data Email : jaranitk@biophics.org

Facility Contact Backup First Name : Jetsumon Middle Name : Last Name : Prachumsri

Degree : PhD Phone : +66 2 306 9187 Ext. : No Data Email : jetsumon.pra@mahidol.edu

Investigator Name First Name : Assoc. Prof. Jaranit Middle Name : Last Name : Kaewkungwal

Degree : PhD Role : Principal Investigator
- Site Name : University of Public Health

City : No Data	State/Province :	Postal Code :
Country : Myanmar	Recruitment Status : Recruiting	

Facility Contact First Name : Dr. Pyae Middle Name : Lin Last Name : Aung

Degree : MBBS, MPH Phone : Ext. : No Data Email : pyaelinnag@gmail.com

Facility Contact Backup First Name : Dr. Myat Middle Name : Thu Last Name : Soe

Degree : MBBS, IADCS, IDCS, DTM&H, MCTM, PhD Phone : Ext. : No Data Email : dr.myatthusoe@gmail.com

Investigator Name First Name : Dr. Than Middle Name : Naing Last Name : Soe

Degree : MBBS, DAP&E, MPH, FETP Role : Site Sub-Investigator

Section C : Contact for Public Queries (Responsible Person)

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Postal Address : 420/6 Ratchawithi Road, Ratchathewi		
State/Province : Bangkok	Postal Code : 10400	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Faculty of Tropical Medicine, Mahidol University		

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Assoc. Prof. Jaranit	Middle Name :	Last Name : Kaewkungwal
Degree : PhD	Phone : +66 87 1001951 Ext. : No Data	Email : jaranitk@biophics.org
Postal Address : 420/6 Ratchawithi Road, Ratchathewi		
State/Province : Bangkok	Postal Code : 10400	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Faculty of Tropical Medicine, Mahidol University		

Deidentified Individual Participant-level Data Sharing

Plan to share IPD : No Data

Plan description : No Data

Publication from this study

MEDLINE Identifier : No Data

URL link to full text publication : No Data
