TCTR ID : TCTR20190806004

OTHER ID :

Overall Recruitment Status : Recruiting

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
	Business Email : pornpimon.ada@mahidol.ac.th
	Business Address : 4th Floor, The 60th Anniversary of His Majesty the King's Accession to the Throne Building, Faculty of Tropical Medicine, Mahidol University 420/6 Ratchawithi Road, Ratchathewi, Bangkok 10400, Thailand

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
Intervantion 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.
Intervantion 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 Detectio
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 detectio
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

1. 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	

2. 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)

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		

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