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How screening for and treating malaria before surgery affect the overall outcome of surgical patients

Submission date 08/10/2022	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 17/10/2022	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 17/10/2022	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Malaria screening and treatment before and after surgery is not done routinely in the practice of surgery in Ghana. However, there have been reports from a few cross-sectional studies revealing a link between peri-operative malaria infection and poor surgical outcomes in Ghana and other parts of the world. Meanwhile, adverse surgical outcomes continue to pose a significant socio-economic burden on patients, families, communities and health systems globally, particularly in low-middle-income countries like Ghana. We seek to determine the impact of peri-operative malaria screening and treatment on the outcomes of patients who undergoes elective surgeries at the Eastern Regional Hospital, Koforidua.

Who can participate?
Patients at least 6 months old who are to undergo surgery

What does the study involve?
Patients will be divided into two groups. One group will be tested for malaria using microscopy or antigen test. Those who test positive will be given malaria treatment before surgery. Those will test negative will undergo their surgery as planned.

What are the possible benefits and risks of participating?
Benefits: screening and treatment for malaria
Risks: no additional risks

Where is the study run from?
Eastern regional Hospital (Ghana)

When is the study starting and how long is it expected to run for?
July 2022 to November 2022

Who is funding the study?
President's Malaria Initiative, USAID and National Malaria Control Programme (Ghana)

Who is the main contact?
Dr Foster Amponsah-Manu, foster_amponsah@yahoo.com

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
GHS-ERC 021/05/22

Study information

Scientific Title
Impact of peri-operative malaria screening and treatment on surgical outcomes at the Eastern Regional Hospital, Koforidua: a single-blind randomized controlled trial

Acronym
IPMSTSOERHK

Study objectives
There will be no difference between surgical outcomes of patients who are screened and/or treated for malaria peri-operatively and those who are not screened or treated for malaria

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/07/2022, Ghana Health Service Ethics Review Committee (Research and Development Division, P.O. Box MB 190, Accra, Ghana; no telephone number provided; ethics.research@ghsmail.org), ref: GHS/RDD/ERC/Admin/App/22/269

Study design
Single center randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
The effect of perioperative malaria screening on surgical outcomes

Interventions
After consent, an eligible participant will be randomly assigned to either screening or comparison group by a computer generated randomisation scheme. Numbers will be generated randomly and put in an opaque envelope.

Participants in the screening group will be screened perioperatively for malaria parasites using microscopy and those found to have malaria parasitemia will receive standard malaria treatment with artemisinin combination therapy (ACT).

Participants in the control group will not be screened and receive treatment as usual.

These two groups of participants would be followed-up to 30 days post-operation while outcomes including surgical site infection, haemorrhage, prolonged hospitalisation, readmission and death will be assessed and recorded.

Intervention Type
Other

Primary outcome measure
Surgical outcomes measured weekly using patient records for a period of 30 days post-op:
1. Length of hospital stay
2. Development of surgical site infections

3. Hemorrhage
4. Readmission
5. Death

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/07/2022

Completion date
30/11/2022

Eligibility

Key inclusion criteria
1. Patient must be at least 6 months old, since under 6 months and congenital malaria are rare
2. Patient must undergo an elective surgical operation involving greater than or equal to 5cm skin incision
3. Patients who consent to participate in the trial

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
350

Key exclusion criteria
1. Surgical patient with uncompensated comorbidities
2. Patient is undergoing surgery but had previous surgery in the last 30 days and beforetime of recruitment
3. Patient is undergoing surgery but has an active surgical site infection or any other surgical outcome from procedure that took place before time of recruitment

Date of first enrolment
10/08/2022

Date of final enrolment
30/10/2022

Locations

Countries of recruitment
Ghana

Study participating centre
Eastern regional Hospital
P.O. Box 201
Koforidua
Ghana
N/A

Sponsor information

Organisation
President's Malaria Initiative, USAID and National Malaria Control Programme

Sponsor details
National Malaria Control Program (NMCP)
Public Health Division, Ghana Health Service
P.O. Box KB 493
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+233 21661484
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Sponsor type
Government

Website
https://www.pmi.gov/

Funder(s)

Funder type
Government

Funder Name
President's Malaria Initiative

Alternative Name(s)
U.S. President's Malaria Initiative, US President's Malaria Initiative, The President's Malaria Initiative, PMI

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/11/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request
foster_amponsah@yahoo.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			14/10/2022	No	Yes
Protocol file		01/05/2022	14/10/2022	No	No