

# Evaluation of photodynamic therapy (a treatment that involves light-sensitive medicine and a light source to destroy abnormal cells) as a safe and effective treatment for malaria

<b>Submission date</b> 05/09/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 06/09/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 06/09/2022	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Malaria is a disease of great public health concern and it is one of the leading causes of death especially in developing countries and tropical regions of the world. There is still no vaccine available. According to the 2015 World Malaria Report, there were 214 million cases of malaria globally in 2015 (uncertainty range 149–303 million) and 438000 malaria deaths (range 236 000–635 000) representing a decrease in malaria cases and deaths of 37% and 60% since 2000, respectively. The burden was heaviest in the WHO African Region, where an estimated 90% of all malaria deaths occurred, and in children less than 5 years, who accounted for more than two thirds of all deaths.

The study is evaluating if Photodynamic Therapy (PDT; a treatment that involves light-sensitive medicine and a light source to destroy abnormal cells) might be a safe and effective treatment tool for Malaria patients.

### Who can participate?

Adults aged 18 years and above with uncomplicated malaria from Ibadan, Nigeria and its environs.

### What does the study involve?

Patients in the treatment group receive 5 PDT treatments within 14 days and are checked for safety (WBC and PVC) and efficacy of PDT (parasite count).

Patients in the control group receive standard ACT therapy while same measurements are done.

### What are the possible benefits and risks of participating?

Benefits: Faster and more effective parasite clearance and relief of symptoms in treatment group expected.

Risks: Denial of standard ACT therapy

Where is the study run from?  
State Hospital (Nigeria)

When is the study starting and how long is it expected to run for?  
April 2019 to November 2021

Who is funding the study?  
ISLA Research Group and Weber Medical, Germany.

Who is the main contact?  
Robert Weber, robert.weber@webermedical.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
Nil known

## Study information

**Scientific Title**  
Evaluation of anti-microbial photodynamic therapy (using riboflavin as sensitizer) as a safe and effective treatment option for malaria

**Study objectives**

Proof of concept: Anti-microbial photodynamic therapy (using riboflavin as sensitizer) as a safe and effective treatment option for Malaria (p. falciparum). aPDT reduces parasite counts more effectively than conventional ACT treatment.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 10/04/2019, Oyo State Research Ethics Review Committee (Ministry of Health, Department of Planning, Research and Statistics Divison, Oyo State of Nigeria, Nigeria; +234 8116308821; info@oyostate.gov.ng), ref: AD 13/479/1192

### **Study design**

Interventional non randomized

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Malaria (p. falciparum)

### **Interventions**

Comparison between treatment and control group, both composed of patients suffering from Malaria (p. falciparum). Treatment group receives aPDT treatments, control group conventional ACT therapy. No masking. No randomization.

Usage of Riboflavin as photosensitizer. Activation by systemic (intravenous) application of 447nm blue laser light and 370 nm ultraviolet (UVA) light. Subsequent intravenous laser therapy with green, yellow and red light.

Treatment time: 90 min; 5 treatments in total within 14 days.

Follow up on day 28 after first treatment with both groups.

### **Intervention Type**

Mixed

### **Primary outcome(s)**

Parasite count on day 0, day 2, day 4, day 8, day 14 and day 28 by blood test

### **Key secondary outcome(s))**

Safety measurements on day 0, day 2, day 4, day 8, day 14 and day 28 by blood test:

1. White blood cell count
2. Packed cell volume test (hematocrit)

### **Completion date**

01/11/2021

## **Eligibility**

**Key inclusion criteria**

Adults aged 18 years and above with uncomplicated malaria from Ibadan, Nigeria and its environs.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

124

**Key exclusion criteria**

1. Age <18 years
2. Pregnancy

**Date of first enrolment**

01/11/2020

**Date of final enrolment**

01/10/2021

**Locations****Countries of recruitment**

Nigeria

**Study participating centre**

State Hospital

Ring road

Ibadan

Nigeria

10000

**Sponsor information**

**Organisation**

Global Heartbeat e.V.

**Funder(s)****Funder type**

Industry

**Funder Name**

Global Heartbeat e.V.

**Funder Name**

Weber Medical GmbH

**Results and Publications****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