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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

Submission date
05/09/2022

Recruitment status
No longer recruiting

Registration date
06/09/2022

Overall study status
Completed

Last Edited
06/09/2022

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

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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