Mal-Herbal Protocol Version 8 dated 20th August 2020

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Abstract

Background: Malaria is a disease of poverty and is still a major global health problem, especially in Africa. Almost all African countries are located in a malaria-endemic area (Figure 1). It was estimated that 228 million cases of malaria occurred worldwide in 2018.The development of insecticide and artemisinin resistance threatens the gains that have been made in the control and elimination of malaria. Tanzania is among the top ten highest-burden countries in the world. Therefore, the scientific investigation of antimalarial herbal remedies to prove their *efficacy* and safety may be of benefit to the worldwide agenda of malaria control and elimination.

Objective: The first primary objective of this study will be to assess the safety and tolerability of malaria herbal remedy of Maytenus senegalensis among healthy male adults aged 18 to 45 years in Tanzania. The second objective is to evaluate the safety, tolerability as well as efficacy of malaria herbal remedy Maytenus senegalensis (MALHERBAL) for the treatment of Tanzanian adults aged 18 to 45 years with uncomplicated malaria compared to Artemether-lumefantrine.

Materials & Methods: The study design of the trial will be single-center phase IIa and open-label clinical research with a population of 116 male participants aged 18 to 45 years residing in Bagamoyo District or nearby districts. The primary endpoint is the number of adverse events (AE) after drug intake until day 28. Secondary endpoints are the number of serious adverse events (SAE), adequate clinical and parasitological response rate (ACPR) on day 28, clinical and parasitological failure rates on days 3, 7, 14, and 28, changes in hemoglobin/hematocrit until day 28, and fever and parasite clearance time. Oocyst burden on days 7 and 14 as well as theNumber of developed early ring stage *P. falciparum* parasites. Case report form will be used to collect all study endpoint data. Categorical data will be presented by treatment group and time-point using counts and percentages of participants. Continuous variables will be also presented by treatment group and time-point, using (at least) the mean, standard deviation (SD), median, minimum (Min), maximum (Max), and number of observations (N). The analysis will be descriptive. In addition, 95% Confidence Intervals will be computed by the treatment group for all the efficacy end-points.

Attachments

PDF

Mal-Herbal Protocol ...

1.7MB