Clinical Evaluation of the quality, safety and effectiveness of Mist Amen Fevermix, a Ghanaian Bi-Herbal Product, Used in the Management of Uncomplicated Malaria

Medicinal plants and products have been used in the treatment of diseases all over the world throughout the history of mankind. Over time in some countries, they have been integrated into the public healthcare system but in the case of Ghana, integration is at the pilot stage. However, questions related to the safety and effectiveness of these medicinal plants and products have been raised on account of lack of standardization and good manufacturing practices. Malaria is a disease of public health concern and continues to be a major cause of morbidity and mortality in most tropical and subtropical countries. The influx of fake medicines and drug counterfeiting has facilitated the malaria parasites becoming resistant to most medicines and has led to an urgent need for new effective antimalarials. This research was aimed at determining the quality, safety and effectiveness of Mist Amen Fevermix a decoction of the stem bark of *Morinda lucida* and *Parinari robusta* in the treatment of uncomplicated malaria in humans at the Tafo Government Hospital, Kumasi after Committee on Human Research, Publication and Ethics (SMS/KNUST) approval. In this research, an attempt was made to develop quality standardisation methods for Mist Amen Fevermix on the basis of macroscopic, microscopic and physicochemical parameters. The set parameters were found to be sufficient to evaluate Mist Amen Fevrrmix and can be used as reference standards for the quality control purposes. Clinically established malaria in male and female patients aged, 15-60 years were treated with Mist Amen Fevermix, and at the specified dose of 45 ml (0.45 g) three times daily for seven days. Participants were reviewed and monitored on days; 3, 7, 14 and 28. There was a complete treatment of 82.35 percent within the first three days in participants and a statistically significant difference between the mean levels of malaria parasites recorded at the first visit and those recorded during review on the second visit, $t(34) = 12.20$, $p = .000$. Similarly, there was statistically significant difference between the levels of malaria parasites recorded on the second visit and that of the third visit, $t(24) = 2.50$, $p = .022$. This shows the effectiveness of Mist Amen Fevermix in the treatment of malaria. Kidney and liver function tests as well as full blood count were within normal reference range at the end of the study and thus established the safety of Mist Amen Fevermix in human aged 15-60 in the treatment of uncomplicated malaria.