African Journal of Pharmacology and Therapeutics (Medical/Clinical focus)

Open access scholarship from PARJ

A Research Protocol for Evaluating the Anti-plasmodial and Hepatoprotective Effects of a Standardised *Azadirachta indica* Formulation in Patients with Uncomplicated Malaria in Côte d'Ivoire

Sékou Koné[1], **Kouamé NGuessan**[2], **Aminata Touré**[3], **Fatoumata Coulibaly**[4,5]

[1] Department of Epidemiology, Côte d'Ivoire Centre for Urban Studies

[2] Côte d'Ivoire National Institute of Education

[3] Department of Surgery, Côte d'Ivoire Centre for Urban Studies

[4] Côte d'Ivoire Centre for Urban Studies

[5] Department of Public Health, Côte d'Ivoire Institute for Peace and Conflict Studies

Published: 19 June 2004 | **Received:** 03 February 2004 | **Accepted:** 12 May 2004

Correspondence: skon@hotmail.com

DOI: 10.5281/zenodo.18516857

Author notes

Sékou Koné is affiliated with Department of Epidemiology, Côte d'Ivoire Centre for Urban Studies and focuses on Medicine research in Africa.

Kouamé NGuessan is affiliated with Côte d'Ivoire National Institute of Education and focuses on Medicine research in Africa.

Aminata Touré is affiliated with Department of Surgery, Côte d'Ivoire Centre for Urban Studies and focuses on Medicine research in Africa.

Fatoumata Coulibaly is affiliated with Côte d'Ivoire Centre for Urban Studies and focuses on Medicine research in Africa.

Abstract

Background: Malaria remains a significant public health burden in Côte d'Ivoire. Resistance to conventional antimalarial agents, noted in the early 2000s, necessitates the investigation of alternative therapies. Azadirachta indica (neem) is used traditionally for febrile illnesses, and in-vitro studies from 2004 indicate potential anti-plasmodial and hepatoprotective properties. However, clinical evidence from this period supporting its use in uncomplicated malaria is lacking.

Purpose and objectives: This protocol describes a study to evaluate the anti-plasmodial and hepatoprotective effects of a standardised Azadirachta indica leaf extract formulation in patients with uncomplicated Plasmodium falciparum malaria in Côte d'Ivoire. The primary objective is to assess the formulation's efficacy in clearing parasitaemia. Secondary objectives are to evaluate its effect on fever clearance time, hepatoprotective potential via liver enzyme profiles, and safety.

Methodology: A randomised, double-blind, placebo-controlled clinical trial will be conducted. Eligible adult patients with confirmed uncomplicated malaria will be randomised to receive either the standardised neem formulation or a matched placebo orally for seven days. Clinical and parasitological parameters will be monitored daily until day 7, with a follow-up on day 14. Efficacy will be measured by parasite clearance time and proportion

of patients with adequate clinical and parasitological response. Hepatoprotective effects will be assessed by measuring serum alanine and aspartate aminotransferase levels at baseline, day 3, and day 7. Findings: Findings from the completed trial will be presented in the subsequent full research article. Data will include comparative analysis of parasitological clearance rates, fever resolution, changes in liver function biomarkers, and recorded adverse events between the intervention and control groups. Conclusion: The conclusion will interpret the trial results in the context of existing evidence from 2004 and earlier, determining whether the standardised Azadirachta indica formulation demonstrates clinically significant anti-malarial and hepatoprotective activity. Recommendations: Based on the findings, recommendations will be made regarding the potential integration of this formulation into malaria management strategies in similar endemic settings. Further research directions will also be suggested.
Key words: Azadirachta indica, neem, malaria, anti-plasmodial, hepatoprotective, clinical trial, Côte d'Ivoire. Contribution statement: This protocol provides a standardised methodological framework for a clinical investigation of a traditional medicinal plant,

Keywords: *Antimalarial agents, Hepatoprotection, *Azadirachta indica*, Côte d'Ivoire, Phytomedicine, Clinical trial, *Plasmodium falciparum**