PERFORMANCE OF RAPID IMMUNOCHROMATOGRAPHIC TEST AND MICROSCOPY IN DETERMINATION OF MALARIA PREVALENCE AMONG EXPECTANT WOMEN IN KERICHO COUNTY HOSPITALS, KENYA

Annastasia Wangari Njeru (B. Sc.)
Reg No: 156/24975/2012

Signature .................................. date 22/09/14
Department of Zoological Sciences

A Research Proposal Submitted in Partial Fulfillment of the Requirements for the Award of a Degree of Master of Science (Immunology) in the School of Pure and Applied Sciences of Kenyatta University

SUPERVISORS

Dr. Joshua Mutiso
Department of Zoological sciences
Kenyatta University
Nairobi, Kenya

Signature .................................. Date 23/9/2014

Dr. Erick Mibei
School of Health Sciences
University of Kabianga
Kericho, Kenya

Signature .................................. Date 22/09/14
ABSTRACT

Malaria, a parasitic infection transmitted by mosquitoes, is one of the most devastating infectious diseases and contributes very significantly to maternal and foetal mortality. Microscopic analysis has been the standard diagnostic technique for identifying malaria infections for more than a century but is unable to detect all infections as parasites can be sequestered in the placenta. Good quality microscopy is also lacking in many resource-limited settings, as it requires well-trained, competent personnel, infrastructure as well as effective quality control and assurance. It is also labour-intensive and time-consuming, sensitivity decreases as the density of malarial parasites in the blood decreases. The problems associated with implementing and sustaining a high level of skilled microscopy appropriate for clinical diagnosis, particularly in the field setting, have prompted the development of a variety of technologically simple malaria rapid diagnostic tests. Rapid immunochromatographic test may provide a solution as emerging evidence suggests that they are capable of detecting *Plasmodium falciparum* which sequesters in the intervillous space of the placenta better than microscopy. The proposed study aims at evaluating the performance of the rapid immunochromatographic strip test and microscopy in determination of malaria prevalence during pregnancy using polymerase chain reaction as a confirmatory test. The study targets the primary health care setting using Kericho District Hospital, Kipsitet and Fort Ternan Health Centres which represent resource-limited setting, reliant on microscopy as malaria diagnostic test. They lack well-trained, competent personnel, infrastructure as well as effective quality control and quality assurance to make accurate diagnosis. Participants will be drawn from a population of pregnant women aged 18 years and above, who have malaria symptoms and are not on antimalarial drugs attending antenatal care visits. Using microscopy as the gold standard, Polymerase Chain Reaction as a confirmatory test, the sensitivity, specificity, negative predictive value and positive predictive value of the IC test will be determined. The prevalence of malaria among expectant mothers will also be determined using microscopy and rapid ICTs. Data analysis will be done using SPSS version 17. McNemar's Chi square statistic will be used to test the level of agreement between the two tests. The findings of this study will be crucial in determining the suitability and reliability of rapid immunochromatographic test that will allow community health care workers to make rapid and accurate diagnosis of malaria in expectant mothers and make immediate therapeutic decisions.
LIST OF ACRONYMS AND ABBREVIATIONS

ACT  Artemisinin-combination therapy
CDC  Centre for Disease Control
CI   Confidence interval
CSA  Chondroitin sulfate
DDT  Dichlorodiphenyltrichloroethane
DNA  Deoxyribonucleic Acid
EDTA Ethylenediamine tetra-acetic acid
HRP-2 Histidine Rich Protein-2
ICT  Immunochromatographic test
IREC Institutional Research and Ethics Committee
IRS  Indoor residual spraying
ITNs Long-lasting insecticidal bed nets
KDH  Kericho District Hospital
LBW  Low birth weight
mAbs Monoclonal antibodies
MRDDs Malaria rapid diagnostic Devices
NPV  Negative predictive value
PCR  Polymerase chain reaction
P. F  Plasmodium falciparum
PfEMP 1Plasmodium falciparum erythrocyte membrane protein-1
pLDH Plasmodium lactate dehydrogenase
PPV  Positive predictive value
RDTs  Rapid diagnostic tests
SSA   Sub-Saharan Africa
SPSS  Statistical package for the social sciences
TDR   Research and Training in Tropical Diseases
WHO   World Health Organization