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## Pharmacovigilance of artemether lumefantrine in pregnant women followed until delivery in Rwanda

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The World Health Organization presently recommends Artemisinin-based combination therapy (ACT) as first-line therapy for uncomplicated P. falciparum malaria. The artemisinin derivative artemether, in combination with lumefantrine is currently used in Rwanda for malaria during the second and third trimesters of pregnancy. Safety data on the use of ACT in pregnancy are still limited though and more data are needed. In this pharmacovigilance study, the exposed group (pregnant women with malaria given artemether-lumefantrine), and a matched non-exposed group (pregnant women without malaria and no exposure to artemether-lumefantrine) were followed until delivery.

The outcomes for the total sample of 2,050 women were for the treatment (n=1,072) and control groups

(n=978) respectively: abortions: 1.3% and 0.4%; peri-natal mortality 3.7% and 2.8%; stillbirth 2.9% and 2.4%; neonatal death [less than or equal to 7 days after birth 0.5% and 0.4%; premature delivery 0.7% and 0.3%; congenital malformations 0.3% and 0.3%. A total of 129 obstetric adverse events in 127 subjects were reported (7.3% in the treatment group, 5.0% in the control group). In a multivariate regression model, obstetric complications were more frequent in the treatment group (OR (95% CI): 1.38 (0.95, 2.01)), and in primigravidae (OR (95% CI) 2.65 (1.71, 4.12) and at higher age (OR per year: 1.05 (1.01-1.09).

There were no specific safety concerns related to artemether-lumefantrine treatment for uncomplicated falciparum malaria in pregnancy. However, more obstetric complications were observed in the treatment group. These increased occurrence of complications could, however, be caused by the malaria episode itself, but further assessment is required.

## Biography

Stephen Rulisa is an obstetrician-gynecologist at Kigali University Teaching hospital & Head of Clinical Research department at same institution and Ph.D. fellow at Academic medical Centre, University of Amsterdam, The Netherlands. He is a lecturer at National University of Rwanda, School of Medicine and Head of department of Obstetrics & gynecology at the school of medicine. He is the Secretary General, Rwanda Society of Obstetrics & Gynecology (RSOG). He was Former President of Rwanda Medical Association (2009-2011).He is a member of University Research council and there committees on education and training. His research interest is infectious diseases, reproductive health with special focus on improving pregnancy outcome.

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