

Largest ever clinical trial on malaria during pregnancy in Africa

A four-year study shows four available antimalarial treatments are safe to use in pregnancy, providing sound scientific evidence on their use

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Dit is de omschrijving

A four-year study (2012-2015), led by the Belgian Institute of Tropical Medicine Antwerp (ITM) and coordinated by Professor Umberto D'Àlessandro, shows four available antimalarial treatments are safe to use in pregnancy, providing sound scientific evidence on their use. The results of the PREGACT study (PREgnancy Artemisinin-based Combination Treatments), which involved over 3000 women in Burkina Faso, Ghana, Malawi and Zambia, appear this week in the leading New England Journal of Medicine.

Pregnant women are more vulnerable to malaria, a parasitic disease which still causes nearly 600,000 deaths each year, most of them young children in Sub-Saharan Africa. Expecting women with malaria often become anemic and deliver smaller babies, which have a higher risk of dying before their first year of life. As pregnant women are systematically excluded from most clinical trials, information on the safety and efficacy of current antimalarials in pregnancy is scarce, especially in Africa.

The PREGACT study compared the safety and efficacy of four artemisinin-based combination treatment (ACTs): amodiaquine-artesunate (AQAS), dihydroartemisinin-piperaquine (DHAPQ), artemether-lumefantrine (AL), and mefloquine-artesunate (MQAS). A total of 3,428 pregnant women with malaria in the second and third trimester were randomly assigned to one of these treatments. The study, funded by the European and Developing Countries Clinical Trials Partnership (EDCTP) and the Bill & Melinda Gates Foundation, made a head-to-head comparison between these treatments to determine their pros and cons - an approach unlike most pharmaceutical research.

The researchers conclude that all four treatments, which are already used in adults and children, were effective and safe, but there were some differences among them. The women who took AL had fewest complications, acceptable cure rates, but the shortest protection against re-infection. DHAPQ was the most effective treatment, with good safety, and longer protection from re-infection after treatment.

"We hope that the use of these ACTs among pregnant women will now increase," said Prof. Umberto D'Àlessandro, the study's coordinating investigator, who is affiliated with the

Antwerp Institute of Tropical Medicine (ITM), the Medical Research Council

Unit The Gambia (MRCG) and the London School of Hygiene and Tropical Medicine (LSHTM). "These results provide strong support for the use of ACTs in the second and third trimester of pregnancy and will help African countries in either confirming or changing their treatment guidelines for pregnant women with malaria. Even though ACTs are already recommended for pregnant women in the 2nd and 3rd trimester, some of them may still receive quinine, an old drug with many side effects."

The study results also provide information regarding the most adequate treatment according to the local malaria situation. For example, in regions where malaria transmission is intense, like in Burkina Faso, women can experience several malaria infections in a limited time span. In such cases, a treatment providing several weeks protection, such as DHAPQ, would be the best choice. Where transmission is less intense, other treatments could be used.

The researchers also reported their findings to the World Health Organization (WHO) to inform the future updates of the WHO guidelines on malaria in pregnancy.

"Pregnant women in Africa are at increased risk of malaria infection and its harmful consequences for both themselves and their foetus. Identifying safe and effective treatment regimens is a priority for malaria control programmes. The results presented today are a major contribution to the management of malaria in this at-risk and vulnerable group," said Dr. Pedro Alonso, Director of the Global Malaria Programme at the World Health Organization.

Prof. Feiko ter Kuile, coordinator of the Malaria in Pregnancy Consortium, said: "The results of this trial, which is the largest comparative malaria treatment trial for pregnant women in Africa to date, is excellent news for policy makers and pregnant women as it shows that all four commonly used artemisinin-based antimalarial combinations appear safe and have excellent efficacy in treating malaria in this high risk group. It thus provides strong support for the current WHO recommendation."

The PREGACT trial was supported by ITM's Clinical Trials Unit and run according to [international methodological and ethical standards](#), which is not to be taken for granted in countries where resources and available infrastructure are limited. Several Master and PhD students were trained in Burkina Faso, Malawi and Zambia in the context of this trial. The trial equipment, such as ultrasound machines, remains operational at the trial sites.

Link

- The article in The New England Journal of Medicine: [Four Artemisinin-Based Treatments in African Pregnant Women with Malaria](#)