

Safety of Hydroxychloroquine in Pregnant Patients With Connective Tissue Diseases: A Study of One Hundred Thirty-Three Cases Compared With a Control Group - PubMed

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Clinical Trial

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Abstract

Objective: The use of hydroxychloroquine (HCQ) in pregnancy remains controversial. The recent demonstration that HCQ passes across the placenta, with cord blood concentrations nearly identical to those found in maternal blood, emphasizes the need for careful evaluation of pregnancies in women receiving HCQ. However, only small series of HCQ-treated pregnant women have been reported, and most of these studies had no control group. We now report our experience with 133 pregnancies in women being treated with HCQ, resulting in 117 live births. Results in the HCQ group are compared with those in a control group.

Methods: One hundred thirty-three consecutive pregnancies in 90 women treated with 200 mg of HCQ either twice daily (122 pregnancies) or once daily (11 pregnancies) were studied. These pregnancies were compared with 70 consecutive pregnancies in 53 women with similar disorders who did not receive HCQ. Electrocardiography was performed in 47 children of mothers treated with HCQ and in 45 children in the control group.

Results: Eighty-eight percent of pregnancies in the HCQ group and 84% of those in the control group ended successfully with a live birth. The outcomes of pregnancy were not statistically different between groups. One child in each group died of causes related to prematurity. Three malformations were observed in the HCQ group (1 hypospadias, 1 craniostenosis, and 1 cardiac malformation) versus 4 in the control group. On the electrocardiograms, the PR interval and the corrected QT interval were not statistically different between groups. No visual, hearing, growth, or developmental abnormalities were reported in any of the children at the last follow-up (ages 12-108 months; mean age 26 months).

Conclusion: Our findings support preliminary evidence for the safety of HCQ therapy during pregnancy. This treatment probably should be maintained throughout pregnancy in patients with systemic lupus erythematosus.

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