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Birth outcomes in pregnant women taking leflunomide.

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OBJECTIVE:: In preclinical reproductive studies, Arava(R) (leflunomide) was embryotoxic and teratogenic. Women treated with leflunomide are advised to avoid pregnancy;those who become pregnantare advised to reduce fetal exposure through a cholestyramine drug elimination procedure. However, little human safety data is available regarding leflunomide-exposed, cholestyramine-treated pregnancies. METHODS:: Sixty-four pregnant women with rheumatoid arthritis (RA) treated with leflunomide (95.3% treated with cholestyramine), 108 pregnant women with RA not treated with leflunomide, and 78 healthy pregnant women were enrolled in a prospective cohort study between 1999 and 2009. Information was collected by maternal interviews, medical records, and a specialized physical examination of infants. RESULTS:: There were no significant differences in the overall rate of major structural defects in the exposed group (3/56 live births or 5.4%) relative to either comparison group (4.2%, 4.2% respectively, p = 0.13). The rate was similar to the 3-4% expected in the general population. There was no specific pattern of major or minor anomalies. Infants in both the exposed and RA comparison groups were born smaller and earlier relative to healthy comparison infants; however, after adjustment for confounders, there were no significant differences between the exposed and disease-matched RA group. CONCLUSIONS:: Although the sample size is small, these data do not support a substantial increased risk for adverse pregnancy outcomes due to leflunomide exposure among women who go through the cholestyramine elimination procedure early in pregnancy. These findings can provide some reassurance to women who inadvertently become pregnant while taking leflunomide and who go through the washout procedure.

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