

1. Arthritis Rheum. 2010 May;62(5):1494-503.

Birth outcomes in women who have taken leflunomide during pregnancy.

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OBJECTIVE: In preclinical reproductive studies, leflunomide was found to be embryotoxic and teratogenic. Women treated with leflunomide are advised to avoid pregnancy; those who become pregnant are advised to reduce fetal exposure through a cholestyramine drug elimination procedure. The present study was undertaken to investigate pregnancy outcomes in women who received leflunomide and were treated with cholestyramine during pregnancy. **METHODS:** Sixty-four pregnant women with rheumatoid arthritis (RA) who were treated with leflunomide during pregnancy (95.3% of whom received 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 via interview of the mothers, review of medical records, and specialized physical examination of infants. **RESULTS:** There were no significant differences in the overall rate of major structural defects in the exposed group (3 of 56 live births [5.4%]) relative to either comparison group (each 4.2%) ($P = 0.13$). 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 leflunomide-exposed and non-leflunomide-exposed RA groups were born smaller and earlier relative to infants of healthy mothers; however, after adjustment for confounding factors, there were no significant differences between the leflunomide-exposed and non-leflunomide-exposed RA groups. **CONCLUSION:** Although the sample size is small, these data do not support the notion that there is a substantial increased risk of adverse pregnancy outcomes due to leflunomide exposure among women who undergo cholestyramine elimination procedure early in pregnancy. These findings can provide some reassurance to women who inadvertently become pregnant while taking leflunomide and undergo the washout procedure.

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