Study Finds No Link in OC Exposure, Birth Defects

BY SHARON WORCESTER Southeast Bureau

ST. PETERSBURG, Fla. — Contraceptive exposure to oral contraceptives was not associated with increased risk of adverse fetal outcomes in a recent prospective study.

None of the 45 women who were exposed to oral contraceptives during the periconceptional period and were followed until delivery gave birth to an infant with congenital malformations, compared with 6 of 225 controls.

The difference in the congenital malformation rate between the exposed and control group was not significant, according to H.K. Ahn, M.D., and colleagues of the Motherrisk Program at Sungkyunwan University, Seoul, South Korea, during a poster presentation at the annual meeting of the Teratology Society.

The groups were also similar in regard to mean gestational age at delivery (39 weeks in both groups) and birth weight (3,257 g in the exposed group, and 3,268 g in the controls), the investigators said.

Prevention of oral contraceptives that contained both combined ethinyl estradiol and progesterone, or high-dose progestins.

Although some early studies suggested a link between oral contraceptive use during pregnancy and increased risk of birth defects, later studies—including the current study—have failed to reproduce these findings.

"Exposure to oral contraceptives, including those with high doses of progesterone, did not increase adverse fetal outcomes," the investigators said.

Neurocognitive Is Unimpaired By Diclectin

ST. PETERSBURG, Fla. — Diclectin used for nausea and vomiting of pregnancy does not appear to affect the later neurocognitive development of children who are exposed to the drug in utero, Irene Nulman, M.D., and her colleagues at the Hospital for Sick Children, Toronto, reported at the annual meeting of the Teratology Society.

The drug, available in Canada but not in the United States at this time, has proved safe in terms of fetal dysmorphology, but its effects on the central nervous system have been unclear, the investigators reported in a poster presentation at the meeting.

In a prospective, randomized, double-blind, placebo-controlled study of multiethnic, multi ЛАSTERs in elderly women receiving glucocorticoid treatment, the overall safety and tolerability profiles of FOSAMAX® 5 and 10 mg/day were generally similar to those of placebo, but each was associated with the investigator’s diagnosis of possibly, probably, or definitely drug related in 6% of patients treated with either FOSAMAX® 5 or 10 mg/day or placebo.

In two identically designed, three-year, placebo-controlled, double-blind, multicenter studies (United States and Multinational, n=5548), discontinuation of therapy due to any clinical adverse experience occurred in 9.1% of 3236 patients treated with FOSAMAX® 5 mg/day for 2 years and 10 mg/day for either 1 year or 2 additional years and 10.1% of 3223 patients treated with placebo. Discontinuations due to severe gastrointestinal adverse experiences were infrequent. The incidence of fractures at vertebral or non-vertebral sites, gastric or duodenal ulcer, and acute pancreatitis was generally similar to that during the first three years of the study.

The overall safety and tolerability profiles of FOSAMAX® 5 mg/day and FOSAMAX® 10 mg/day were similar. The adverse experiences considered possibly, probably, or definitely drug related in 6% of patients treated with either FOSAMAX® 5 mg/day or placebo.

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