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## Neonatal Lupus Study Seeks Pregnant Women

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ntravenous immune globulin has been suggested as a possible therapy for preventing congenital heart block caused by neonatal lupus, and early data from a study of the treatment indicate that further study is warranted.

Of five women with a previous fetus affected by neonatal lupus—who thus are at increased risk of having a baby with congenital heart block—who were enrolled at press time in the Preventive IVIG Therapy for Congenital Heart Block (PITCH) study, three had given birth to babies without congenital heart block following IVIG treatment, one was still undergoing treatment but showed no fetal echocardiographic evidence of congenital heart block, and one had not reached 12 weeks' gestation and therefore had not begun treatment, principal investigator Dr. Jill Buyon said during an informational teleconference on the study. At least 19 total patients are needed to adequately power this open-label first- phase of the PITCH study, which is sponsored by New York University and the Alliance for Lupus Research, said Dr. Buyon, professor of medicine and vice chair of the department of rheumatology at New York University.

An additional 35 patients will be needed for the second phase of the study, which will proceed if fewer than 3 of the 19 women in the first phase have children with second- or third-degree heart block.

Neonatal lupus can affect babies of mothers with SSA/Ro and SSB/La autoantibodies, and can appear as a transient rash that disappears by the time the baby is about 6 months old, or, in rare cases, as a transient abnormal blood or liver condition. In some cases, however, congenital heart block occurs in affected fetuses, causing permanent heart damage and fetal death.

The risk of congenital heart block is about 2% in a first pregnancy for women with anti-Ro and anti-La antibodies, but the risk jumps to 20% in subsequent pregnancies in women who have had a previous child with congenital heart block or neonatal lupus-related rash, coinvestigator Dr. Deborah Friedman of St. Barnabas Medical Center in Livingston, N.J., said.

Since no therapy has been successful for the treatment of complete heart block, the focus has shifted to prevention of the condition, which appears to occur because of scarring of the conduction system that results from inflammation triggered by the mother's antibodies.

The scarred heart beats extremely slowly, and 20% of affected babies die-most of them within 2 weeks and in utero. Surviving babies almost always require permanent implantation of a pacemaker.

Giving IVIG to at-risk mothers was suggested as a potential preventative therapy because it has the potential to lower maternal antibody levels, thereby reducing fetal exposure, and also to influence effector mechanisms in the fetus itself. Furthermore, IVIG has been shown to be safe in pregnancy, Dr. Buyon noted.

Having a total of 19 women enrolled in the first phase of PITCH will provide adequate power to demonstrate a reduction of risk from 20% to 5% in women with a previously affected child. Patients will receive 400 mg/kg IVIG every 3 weeks for a total of five treatments from weeks 12-24 of pregnancy.

IVIG will be considered efficacious and worthy of further study if fewer than six women in phase II of PITCH have a child with advanced heart block.

Participants should be aged 18-50 years, have a current intrauterine pregnancy of less than 12 weeks, and have circulating SSA/Ro and/or SSB/La antibodies. Participants also should have a previous child with congenital heart block of any degree, which has been documented by EKG and/or echocardiogram; with confirmed characteristic lupus rash; or with congenital heart block and rash.

Women with rheumatic disease can participate if they aren't taking more than 20 mg/day of prednisone. Other exclusion criteria include conditions that would contraindicate the use of IVIG such as a prior serious IVIG infusion reaction, known IgA deficiency, intolerance of volume load, and nephrotic syndrome. Those with a fetus with structural lesions that could cause congenital heart block also are excluded.

Those interested in enrolling patients in PITCH should refer to ClinicalTrials.gov identifier NCT00460928, and should contact research administrator, Lena Geffrard, by calling 212-263-2255 or sending an email to geffrl01@med.nyu.edu.



tests showed no clinically significant changes in serum glucose levels from baseline to cycle six. A small proportion of women will have persistent hypertriglycendema while using oral contraceptive. Changes in serum triglycendes and lipoprotein levels have been reported in combination hormonal contraceptive users. 9. ELEVATED BLOOD PRESSURE. An increase in blood pressure has been reported in combination for grad contraceptives and this increase is more lakely in older oral contraceptive users and with continued use. Data from the Royal College of General Practitioners and subsequent randomized trials have shown that the incidence of hypertension increases with increasing concentrations of projectogenes. Women with a inscript of hypertension religious diseases, or reflat disease increases with increasing concentrations of projectogenes. Women with a inscript of hypertension between diseases and it significant elevation of blood pressure occurs. NureRing® should be discontinued. For most women elevated blood pressure value from normal after scoppin formonal contraceptives, and there is no difference in the occurrence of hypertension between former and never-users. 10. HEADACHE. The onset or exacerbation of migratine or development of headache with a new pattern which is recurrent, persistent, or severe requires discontinued for MuvaRing® and evaluation of the causes. 11. BLEEDING IRREGULARITIES. Bleeding Platforms. Breakthrough bleeding and spotting are sometimes encountered in women using NuvaRing®. If abnormal bleeding will be used using possible or size severe, appropriate investigation should be instituted to rule out the possibility of organic pathology or prognancy, and appropriate treatment should be instituted to the US-Caradian study (n=1177, he percentages of subjects with breakthrough bleedings) gloring ranged from 72 to 11.7% during cycles 1–13. In the two non-US studies, the percentages of subjects with breakthrough bleedings/posting ranged from 72 to 11.7% during cycles 1–13. In the two non-US studi

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