



NEW YORK UNIVERSITY SCHOOL OF MEDICINE

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RE: Research Opportunity - *Preventive IVIG Therapy for Congenital Heart Block (PITCH Study)*

The research team working on Neonatal Lupus Congenital Heart Block, including the Research Registry of Neonatal Lupus, under the direction of Dr. Jill P. Buyon, is pleased to announce the launching of a new research opportunity. We have assembled the resources to embark on a trial of prophylactic treatment to try to prevent congenital heart block BEFORE it begins. Everyone can get treated – there is no placebo or “dummy” group.

The challenge of this project is that we need to enroll patients who have had a prior affected child with heart block or rash, in whom the recurrence rate is 1 in 5, BEFORE the 2 month pregnancy point. In other words, as soon as a woman with a previously affected child knows she is pregnant, and before 12 weeks of gestation, we need her full participation. WE NEED YOUR HELP!

The study involves receiving 5 separate infusions of intravenous immune globulin, a human blood product, beginning at about 2 months of pregnancy and continuing every few weeks through the 7th month. Some extra blood specimens will also be obtained from you on these occasions. The product has been used for many years during pregnancy and is safe. The rest of your health care will follow the rigorous, close monitoring, including fetal echocardiograms, which we recommend in such pregnancies. There is no charge to you.

This study, although time consuming on your part and involving extra blood sticks and drug infusions, has the potential to protect your fetus from the nearly 20% chance (1 in 5) of developing a very serious heart condition, congenital heart block, at very low risk.

If you are interested or simply want more information, please contact Dr. Jill P. Buyon, rheumatologist, at 212-263-0746 jill.buyon@nyumc.org, Lena Geffrard, M.P.H., Research Coordinator, at 212-263-2255 geffr101@med.nyu.edu, or Dr. Deborah M. Friedman, pediatric cardiologist, at 973-322-5691 dfriedman@sbhcs.com

Thank you for your cooperation, and we look forward to hearing from you.

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