OTIS Collaborative Research

OTIS pregnancy studies aim to determine the effects, if any, of medications, vaccines, and health conditions during pregnancy. The availability of such information allows women and their health care providers to make informed choices about treatment, and help improve outcomes for mothers and their babies. Pregnant women enroll themselves into the studies. All of the studies are prospective, observational studies that involve 2-4 phone interviews, release of medical records for pregnancy, and some studies include a free, non-invasive specialized pediatric exam. In addition to collecting information about a woman’s pregnancy, OTIS also provides women with safety information on pregnancy exposures.

Current Studies . . .

Autoimmune Diseases in Pregnancy Project

The Autoimmune Diseases in Pregnancy Project is a North American study that began in 2000 and is projected to continue enrollment through 2015. The study is under the direction of Drs. Kenneth Jones and Christina Chambers at the University of California, San Diego. Initially, the study was sponsored by Aventis Pharmaceuticals and its purpose was to determine if there was an increased risk for major malformations or a pattern of minor malformations in the children of women who were exposed to leflunomide for the treatment of rheumatoid arthritis during the first trimester. Risks for reduced birth size, postnatal growth deficiency, prematurity, miscarriage, or stillbirth are also evaluated. Since then, seven more pharmaceutical companies have joined the project: Abbott Laboratories, Amgen, Apotex, Bristol-Myers Squibb, Heritage, Sandoz and Teva. The focus of the study was broadened to include other autoimmune diseases, such as ankylosing spondylitis, Crohn’s disease, psoriasis, and psoriatic arthritis, as well as the treatment of these diseases in pregnancy. Women who have been diagnosed with one of the conditions above, or women who are being treated with adalimumab, abatacept, etanercept, or leflunomide, are eligible for the study. Women with a diagnosis of an autoimmune disease but who are not taking one of the medications being studied serve as a diseased-matched comparison group. The project also enrolls women without autoimmune disease to serve as a non-diseased comparison group. The goal is to recruit approximately 1650 women over a period of 15 years.

Vaccine and Medications in Pregnancy Surveillance System (VAMPSS)

The Vaccines and Medications in Pregnancy Surveillance System (VAMPSS) is a nationwide post-marketing surveillance system established to comprehensively monitor the use and safety of vaccines and medications during pregnancy through the support of the U.S. Office of Biomedical Advanced Research and Development Authority
(BARDA) and the Agency for Healthcare Research and Quality (AHRQ). The VAMPSS program began in 2009. The program is coordinated by the American Academy of Allergy Asthma and Immunology (AAAAI) and involves both prospective registry surveillance and case-control surveillance to study the safety of exposures in pregnancy. The prospective surveillance arm of VAMPSS is coordinated under the direction of Drs. Kenneth Jones and Christina Chambers at the University of California, San Diego. This arm of the study involves prospective enrollment and follow-up of pregnant women exposed to vaccines and medications during pregnancy. Outcomes among participants exposed to a vaccine or medication under evaluation are compared to outcomes among participants not exposed. The two projects of the VAMPSS study, as they relate to the prospective surveillance arm, are described below.

**H1N1 Vaccine, Seasonal Influenza Vaccine and Antiviral Medications in Pregnancy- A VAMPSS project**

The purpose of the H1N1 vaccine, Seasonal influenza vaccine and Antiviral medications in pregnancy project is to research the safety of influenza vaccines and antiviral medications used to prevent or treat influenza during pregnancy. Women with exposure to the H1N1 vaccine, seasonal influenza vaccine or antiviral medications, such as Tamiflu® (oseltamivir) and Relenza® (zanamivir) during pregnancy, are eligible for the study. Women without exposure to these vaccines and medications may qualify as controls for the study. The goal is to recruit approximately 1100 women over a two year period.

**Asthma Medications in Pregnancy Surveillance System- A VAMPSS project**

The Asthma Medications in Pregnancy Surveillance System (AMPSS) is sponsored by the Agency for Healthcare Research and Quality (AHRQ). AMPSS is researching the use of short-acting vs. long-acting beta-agonists for the treatment of asthma in pregnancy. Women with a diagnosis of asthma who have had exposure to either of these types of beta-agonists during their pregnancy are eligible for the study. Women without exposure to asthma or asthma medications during pregnancy may qualify as controls for the study. The goal is to recruit approximately 600 women over a five year period.

VAMPSS will evaluate risk or safety of vaccines and medications used during pregnancy, with respect to spontaneous abortions, preeclampsia, fetal deaths, preterm births, intrauterine growth restriction, total major congenital malformations, and specific major malformations. In addition, the case-control component of VAMPSS provides exposure prevalence data drawn from a population-based sample.

For more information about the OTIS pregnancy studies, call (877) 311-8972 or visit us online at: [www.OTISpregnancy.org](http://www.OTISpregnancy.org).