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FIRST RESULTS FROM THE PROSPECTIVE GERMAN PREGNANCY REGISTER RHEKISS

A. Strangfeld*¹, C. Bungartz¹, J. Richter², A. Zink^{1,3}, M. Schneider², J. Listing¹, R. Fischer-Betz²

¹German Rheumatism Research Centre, Berlin, ²Policlinic of Rheumatology, Hiller Research Unit, University Clinic Duesseldorf, Heinrich-Heine-University, Düsseldorf, ³Charité University Medicine, Berlin, Germany

My abstract has been or will be presented at a scientific meeting during a 12 months period prior to EULAR 2016:

No

Is the first author applying for a travel bursary and/or an award for undergraduate medical students?: No

Background: There is limited evidence regarding the safety of pharmacologic treatments during pregnancy. With the increasing number of new medications available for the treatment of rheumatic and autoimmune diseases, there is a growing need for systematic collection of prospective real-world data on drug safety in pregnancy and lactation.

Objectives: To determine the safety of various drug treatments during pregnancy and the influence of the underlying rheumatic disease on outcome and child development.

Methods: The Rhekiss register is designed as a prospective nationwide, web-based longitudinal observational cohort study. Pregnant patients with confirmed diagnose of inflammatory rheumatic disease are eligible to be enrolled until the 20th week of pregnancy regardless of drug treatment. Rheumatologists as well as patients report three times during pregnancy (each trimester) and semi-annually after birth until the child's 2nd birthday. Patients can use the online documentation system remote or in the practice.

Information on all given drug treatments, details on the course of the maternal disease, the development of the pregnancy, maternal or fetal complications during pregnancy, pregnancy outcomes, and child development during the first two years of life are collected. At baseline, sociodemographic parameters, prior pregnancies, and comorbidities are reported.

The register is designed as uniform platform with specific modules for various inflammatory rheumatic diseases. Only pseudonymized data are used, data security issues conform with regulatory authorities have been implemented.

It can be easily extended and translated to other languages.

Results: The register started on 15th of September 2015. Until end of January 2016, 106 rheumatologists in outpatient clinic or private practices signed up for participation. Among these, 28 units recruited patients so far. 99 patients were enrolled until end of January. Of these, 26 had rheumatoid arthritis, 26 systemic lupus erythematosus, 17 other connective tissue diseases, 9 juvenile idiopathic arthritis, 8 spondyloarthritis, 7 psoriatic arthritis, 4 autoinflammatory syndromes and 2 systemic vasculitis.

Mean age of the patients was 31.1 (\pm 5.1) years, mean disease duration 6.5 (\pm 8.2) years. Mean disease activity, assessed by the rheumatologist on a numeric rating scale from 0-10, was 2.6 (\pm 2.1) over all diagnoses. On a disease severity scale ranging from 1 to 5 (highest grade), two thirds of the patients were reported as grade 2 or 3.

Conclusions: The German pregnancy register Rhekiss was initiated to fill the knowledge gap on the course and outcomes of pregnancies in patients with rheumatic diseases as well as on the current use and the safety of treatments during pregnancy and lactation. The fast uptake of patients shows that there is a substantial need for and a high interest in real-life data to guide treatment decisions. Rhekiss can be easily extended and translated to other languages.

At the time of the EULAR congress, data on the first seven months of the register will be available for presentation.

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Disclosure of Interest: None declared