Biologics in Pregnancy Up Malformation Risk

By Amy Rothman Schonfeld

PHILADELPHIA — Women with rheumatic disease who took etanercept during pregnancy were three times more likely to have a child with a major malformation than were pregnant women who were not taking the drug, a study presented here today by Christina Myers, M.D., of the University of California in San Diego.

Pregnant women are typically enrolled in the study before they reach 20 weeks of gestation. To be enrolled, the women must have current diagnoses of rheumatoid arthritis (RA), juvenile rheumatoid arthritis, ankylosing spondylitis, psoriasis and psoriatic arthritis, or Crohn’s disease.

Many participants are referred to the OTIS (Organization of Teratology Information Specialists) at the annual meeting of the American College of Rheumatology.


Before pregnancy was confirmed, women were using these medications. Currently are in a situation where con-trol randomized trials typically are not appropriate, yet pregnant women are using these medications. The OTIS project is a prospective, observational cohort study that should shed light on whether the medications are safe for women who are pregnant. However, it will still be several years before all results are in and the data can be statistically ana-lyzed. In the meantime, what can you tell your pa-tients about the use of bi-ologics if they are preg-nant or plan to become pregnant?

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A: There are really sparse data on the safety of biologic agents in women who are pregnant. We currently are in a situation where controlled randomized trials typically are not appropriate, yet pregnant women are using these medications. The OTIS project is a prospective, observational cohort study that should shed light on whether the medications are safe for women who are pregnant. However, it will still be several years before all results are in and the data can be statistically analyzed. In the meantime, what can you tell your patients about the use of biologics if they are pregnant or plan to become pregnant?

Q: If I become pregnant while taking a biologic, what can you tell your pa-tients about the use of biologics if they are pregnant or plan to become pregnant?

A: Information is very limited, but to date neither preclinical data nor clinical data indicate that be-coming pregnant is more difficult. If I become pregnant while taking a biologic drug, do I have a chance of having a baby with a birth defect?

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