UW Health: Seeking participants for study examining allergic reactions to COVID-19 vaccines

Posted on Wednesday, Oct 20, 2021

MADISON, Wis. – Researchers from the UW School of Medicine and Public Health are seeking participants for a clinical study that examines whether the mRNA COVID-19 vaccines (Pfizer/BioNTech and Moderna) pose an increased risk for allergic reactions in individuals who are already considered "highly allergic." Highly allergic individuals are those individuals who've either had an anaphylactic reaction in the last 15 years, are allergic to a medication, or who have a mast cell disorder.

The Phase 2 trial, called Systemic Allergic Reactions to SARS-CoV-2 Vaccination, is sponsored and funded by the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health.

Severe allergic reactions (also known as anaphylaxis) to these COVID-19 vaccinations are quite rare. According to the Centers for Disease Control and Prevention, anaphylaxis has occurred in approximately 2 to 5 people per million vaccinated in the United States.

"While allergic reactions from these vaccines are rare, they do sometimes happen, and most of these reactions have occurred in people with a history of allergies," said Dr. Mark Moss, professor of medicine, UW School of Medicine and Public Health, allergist, UW Health, and principal investigator of the study. "It's critically important for us to better understand who is having negative reactions to the vaccines and why so that we can better advise those individuals who are highly allergic, or who have a mast cell disorder, about the risks and benefits of receiving these two vaccines."

Moss, who serves as director of the clinical research program in the Division of Allergy, Pulmonary and Critical Care Medicine, stresses that, for most people, the benefits of COVID-19 vaccination far outweigh the risks.

The study, which will be conducted at University Hospital under the guidance and supervision of medical staff, will require participants to receive two separate vaccine doses approximately three weeks apart. One out of every 3 participants will receive a placebo (salt water) injection before they receive the first vaccine dose. Participants will not get to choose if they receive the placebo dose, or which vaccine they get. Individuals who initially receive placebo should still receive vaccine, per FDA guidelines, but will require three separate visits.

Medical staff will monitor participants for 90 minutes following each dose to see if they have an allergic reaction. The study team has been trained to recognize and provide treatment for reactions if they occur.

For a week following each dose, participants will be asked to track their symptoms on the study's website or complete a paper form that will be provided at their first visit. Study participants will also receive phone calls to see how they're doing.

To be eligible for the study, individuals must be 12 years of age or older and:

- have a history of severe allergies, **OR**
- have an allergy to a medication, **OR**
- have been diagnosed with a mast cell disorder, **OR**
- have no known history of severe allergies (for a control group)

Parents or legal guardians of 12–17-year-olds who may qualify for the study will need to provide written permission for themselves as well as their children.

Individuals interested in learning more about the study or about their eligibility can call the University of Wisconsin–Madison Allergy Research team at (608) 263-6049.