Clinical trial of AstraZeneca vaccine for COVID-19 resumes at the University of Kansas School of Medicine-Wichita Center for Clinical Research

WICHITA, KANSAS — Recently, the University of Kansas School of Medicine-Wichita Center for Clinical Research resumed leading the local effort of a nationwide clinical trial brought through the COVID-19 Prevention Network testing the COVID-19 vaccine AZD1222, developed by Oxford University and purchased by AstraZeneca.

Regional efforts and testing are being led by KU Medical Center and Children’s Mercy Kansas City. The CoVPN was created by the National Institutes of Health to respond to the growing coronavirus pandemic.

There was a pause in the trial due to a participant outside the United States who had a neurological event. A review was conducted by the FDA and an independent safety review board. It was determined by both the FDA and safety review board that the trial was safe to proceed.

“Pauses in clinical trials are not uncommon,” said Tiffany Schwasinger-Schmidt, M.D., Ph.D., director of the Center for Clinical Research and assistant professor in the KU School of Medicine-Wichita Department of Internal Medicine. “Any time a potential safety concern is raised with a participant, data will be gathered and the information will be reviewed to determine if the safety event could be related to the vaccine or study related medication. Our number one concern as researchers conducting trials are that they are safe, and we take all safety concerns very seriously and review all available data to determine if the trial is safe to continue.”
KU School of Medicine-Wichita Center for Clinical Research resumes clinical trial of AstraZeneca vaccine for COVID-19

Locally, the vaccine will be available at the center and its mobile unit, which will travel to high-risk areas in Wichita and the surrounding region. The mobile unit will arrive in Wichita the week of Thanksgiving and will be located at community partners. It will be in Wichita for two weeks for the initial vaccination and two weeks for the follow-up dose one month later.

The project will be overseen by Schwasinger-Schmidt. Physicians from the Department of Internal Medicine and staff in the Office of Research also will be assisting in conducting the trial.

“We are so excited to have assembled a strong partnership among researchers at KU and Children’s Mercy to offer this vaccination to Kansans,” said Schwasinger-Schmidt. “We know that prevention through vaccination will be key in stopping the spread and devastating effects of this virus.”

The phase 2/3 trial is funded by the NIH and sponsored by AstraZeneca. This study is organized through the Fred Hutchinson Cancer Center, and there will be more than 100 sites nationwide.

There is an overall goal to recruit 1,200 participants in Kansas with 200 being enrolled at the KU Wichita CCR site. Adults over the age of 18 who are considered high-risk for encountering COVID-19 will be recruited into the study, and participants will be randomized to determine who receives the vaccine. Individuals who are staying home and drastically limiting contact with others likely will not be eligible. Two out of every three participants will receive the vaccine, with the third receiving a placebo. Once the trial is concluded, participants receiving the placebo will be eligible to receive the vaccine.

Results of a pilot study of this vaccine were published in the prestigious medical journal, The Lancet, and showed promising results on more than 1,000 clinical trial participants. Side effects appear to be mild as well, with mostly headaches, body aches and fatigue reported. Within these participants, there were no serious adverse events reported.
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To be considered for the clinical trial and receive the vaccine, adults may follow one of these options:

- Register at the Coronavirus Prevention Network website (providing the site preference as KUMC)
- To receive a screening in Wichita, call 316-293-1833.

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MEDIA NOTE: The number above is for those interested in participating in the study. To schedule an interview with Dr. Tiffany Schwasinger-Schmidt or learn more about the study for a story, contact Belinda Venters at 316-706-5945 or bventers@kumc.edu.