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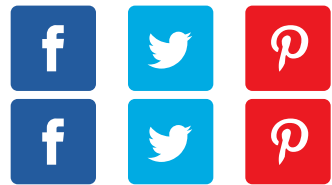
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NIH Concerned About COVID Vaccine Side Effects



By Arthur Allen and Liz Szabo, Kaiser Health News

Monday, September 14, 2020 (Kaiser News) -- [The Food and Drug](#)

Administration is weighing whether to follow British regulators in resuming a [coronavirus vaccine](#) trial that was halted when a participant suffered spinal cord damage, even as the National Institutes of Health has launched an investigation of the case.

“The highest levels of NIH are very concerned,” said Dr. Avindra Nath, intramural clinical director and a leader of viral research at the National Institute for Neurological Disorders and Stroke, an NIH division. “Everyone’s hopes are on a [vaccine](#), and if you have a major complication the whole thing could get derailed.”

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A great deal of uncertainty remains about what happened to the unnamed patient, to the frustration of those avidly following the progress of vaccine testing. AstraZeneca, which is running the global trial of the [vaccine](#) it produced with Oxford University, said the trial volunteer recovered from a severe [inflammation](#) of the spinal cord and is no longer hospitalized.

AstraZeneca has not confirmed that the patient was afflicted with transverse myelitis, but Nath and another neurologist said they understood this to be the case. Transverse myelitis produces a set of symptoms involving inflammation along the spinal cord that can cause pain, muscle weakness and [paralysis](#). Britain's regulatory body, the Medicines and Healthcare Products Regulatory Agency, reviewed the case and has allowed the trial to resume in the United Kingdom.

AstraZeneca “need[s] to be more forthcoming with a potential complication of a vaccine which will eventually be given to millions of people,” said Nath. “We would like to see how we can help, but the lack of information makes it difficult to do so.”

Any decision about whether to continue the trial is complex because it's difficult to assess the cause of a rare injury that occurs during a vaccine trial — and because scientists and authorities have to



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weigh the risk of uncommon side effects against a vaccine that might curb the [pandemic](#).

“So many factors go into these decisions,” Nath said. “I’m sure everything is on the table. The last thing you want to do is hurt healthy people.”

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