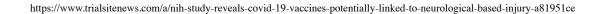


Groups



NIH Study Reveals COVID-19 Vaccines Potentially Linked to Neurological-Based Injury

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TrialSite Staff
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Although small, not yet peer reviewed, and barely mentioned by any media when it first was uploaded to a preprint server three months ago, a National Institutes of Health (NIH)-sponsored observational study in the form of a clinical evaluation involved patients with new onset paresthesia's (abnormal sensations often caused by pressure or damage to peripheral nerves) with or without autonomic symptoms incident to SARS-CoV-2 vaccination and response to immunotherapy with corticosteroids or intravenous immunoglobulin (IVI). This study was led by Principal Investigators affiliated with the National Institute of Neurological Disorders and Stroke, part of the National Institutes of Health, along with a group of respected neurologists employed with Thomas Jefferson University, Icahn School of Medicine at Mt. Sinai, Johns Hopkins University School of Medicine, and Massachusetts General (Department Hospital of Neurology and Pathology/Neuropathology).

What is rare? That's an important question when addressing vaccine injury associated with the COVID-19 vaccine products. Little investigation has gone into this topic which *TrialSite* suggests needs more study. Why does this matter? Even if only a tenth of one percent of those vaccinated lead to injury, this equals 2.2 million persons NIH Study Reveals COVID-19 Vaccines Potentially Linked to Neurological-Based Injury

across America that have new health problems. Of course, that cannot compare to the over one million deaths, and

potentially tens of millions of long COVID cases due to the result of direct SARS-CoV-2 infection. But nonetheless, the U.S. government has an ethical and moral obligation to study and ultimately care for all Americans, including those injured by the novel vaccines introduced into the population as emergency use authorized (EUA) by December 2020.

This study was uploaded to the preprint server earlier this year yet was never published.

The Study

Represented by Corresponding Author Dr. Avindra Nath, this study included 23 self-referred patients evaluated between January to September 2021 for new onset symptoms of polyneuropathy which include sensor, motor, or autonomic presentations within one month of a SARS-CoV-2 vaccination.

Led by the NIH, the study authors utilized the apex research institute's IRB for ethical approval. All patients were evaluated in person (n-13) or television (n=10)while data was abstracted from medical records.

The study team reports in the manuscript uploaded to medRxiv that the study team evaluated the patients for other causes of small fiber neuropathy (SFN). They report two of these possibly vaccine-injured patients presented organ-specific autoimmune disorders, including one with Crohn's disease and the other with Hashimoto thyroiditis in clinical remission at the time of receiving the COVID- 19 vaccine.

What did the authors find?

First, the authors note that all the patients in this study reported symptom onset within three weeks of the administration of the COVID-19 vaccine. 39% developed the symptoms after the second dose, completing the primary mRNA series. 17% reported mild-transient symptoms after the first jab with full onset after the second dose, raising the possibility of immune priming to the spike protein.

The authors note that only one of the patients was observed with evidence of pre-vaccination COVID-19 infection. Cross reactivity between seasonal beta coronaviruses and subunits of the SARS-CoV-2 spike protein might play a priming role.

Conclusion

Several neuropathic symptoms can manifest post COVID-19 vaccine. For some patients there is potentially an immune-mediated process, and this observational study, while small and never peer reviewed, should be better understood with more follow up study.

Study Limitations

The NIH-led study team reports that as this study was observational in nature, involving self-referred patients, the study "is inherently limited by referral bias." While the authors acknowledge the temporal association of the symptoms to the COVID-19 vaccine, they declare the "uncontrolled" study is "limited by referral bias." Dr. Nath and team articulated that they "cannot ascribe it a causative role," and they go on the record that "data from the vaccine trials suggests that such manifestations are very rare."

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References

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