

Researchers suggest ways they could learn by continuing to follow COVID-19 vaccine trial participants

April 13 2021



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Authors from the National Institutes of Health (NIH) and colleagues suggest ways in which we could learn by continuing to follow vaccine trial participants who originally received placebo. They mathematically demonstrate that long-term placebo-controlled vaccine efficacy can be

estimated even after the placebo group has been vaccinated. While less precise than estimates from a standard trial where the placebo group remains unvaccinated, this proposed approach permits assessment of the durability of vaccine efficacy and whether the vaccine eventually becomes harmful to some.

A report is published today in *Annals of Internal Medicine*.

The authors explain that deferred vaccination, if done open-label, may lead to riskier behavior in the unblinded original vaccine group, confounding estimates of long-term [vaccine efficacy](#). Hence, deferred vaccination via blinded crossover, where the vaccine group receives placebo and vice versa, is the preferred way to assess vaccine durability and potential delayed harm. Deferred vaccination allows placebo recipients timely access to the [vaccine](#) when it would no longer be proper to maintain them on placebo, yet still allows important insights about immunologic and clinical effectiveness over time.

More information: Dean Follmann et al. A Deferred-Vaccination Design to Assess Durability of COVID-19 Vaccine Effect After the Placebo Group Is Vaccinated, *Annals of Internal Medicine* (2021). [DOI: 10.7326/M20-8149](#)

Provided by American College of Physicians

Citation: Researchers suggest ways they could learn by continuing to follow COVID-19 vaccine trial participants (2021, April 13) retrieved 17 February 2023 from <https://medicalxpress.com/news/2021-04-ways-covid-vaccine-trial.html>

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