

NIH Opens Long COVID Trials To Evaluate Treatments For Autonomic Nervous System Dysfunction

Part of the RECOVER Initiative, these trials will test at least three treatments for symptoms such as fast heart rate, dizziness and fatigue.

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People 18 years of age and older who are interested in learning more about these trials can visit <https://trials.RECOVERCovid.org/autonomic> or ClinicalTrials.gov and search identifier [NCT06305793](https://trials.RECOVERCovid.org/autonomic), [NCT06305806](https://trials.RECOVERCovid.org/autonomic) and [NCT06305780](https://trials.RECOVERCovid.org/autonomic). Please do not contact the NIH media phone number or email to enroll in these trials.

Two phase 2 clinical trials to test the safety and effectiveness of three treatments for adults with autonomic nervous system dysfunction from long COVID have begun. The autonomic nervous system acts largely unconsciously and regulates bodily functions, such as heart rate, digestion and respiratory rate. Symptoms associated with autonomic nervous system dysfunction have been among those that patients with long COVID say are most burdensome.

The trials are part of the National Institutes of Health's Researching COVID to Enhance Recovery (RECOVER) Initiative, a nationwide research program to fully understand, diagnose and treat long COVID. Other RECOVER phase 2 clinical trials testing treatments to address viral persistence and neurological symptoms, including cognitive dysfunction (like brain fog), launched in July 2023.

"As a long COVID patient, I know firsthand how disruptive and frightening symptoms including rapid heart rate, dizziness and fatigue can be. Patient representatives across RECOVER have also shared that these symptoms are some of the most debilitating symptoms of long COVID," said Heather Marti, co-chair of the RECOVER National Community Engagement Group. "These trials are giving me and others with long COVID hope that it will restore our health and get us back to the lives we so desire."

The two trials, collectively known as RECOVER-AUTONOMIC, are testing three potential treatments in adults who, following COVID-19, now have postural orthostatic tachycardia syndrome (POTS). An autonomic nervous system disorder, POTS is characterized by unexpected fast heart rate, dizziness, fatigue or a combination of these symptoms when a person stands up from sitting or

lying down.

“The trials were developed with input from people living with long COVID, caregivers, community representatives, clinicians and scientists all with unique expertise in the field,” said Gary H. Gibbons, MD, director of the National Heart, Lung, and Blood Institute at the NIH and co-chair of RECOVER. “We are grateful for their collective involvement which significantly shaped the trials and the choice of interventions.”

The trials will initially examine three potential treatments:

- Gamunex-C, a form of intravenous immunoglobulin (IVIG), contains antibodies to help the body protect itself against infection from various diseases and is given by intravenous infusion.
- Ivabradine, an oral medication that reduces heart rate.
- Coordinator-guided, non-drug care, which includes a series of activities managed through weekly phone calls with a care coordinator, such as wearing a compression belt and eating a high-salt diet, which are recommended for patients with POTS to counteract excessive loss of fluids.

“Patients who develop POTS after having COVID-19 are often severely limited by their symptoms, and there are no proven effective treatments,” said Christopher Granger, MD, Duke University Medical Center, who is co-leading RECOVER-AUTONOMIC. “These interventions were selected because they have shown potential benefit in treating symptoms for POTS. The theory we’re testing is that they might also help individuals with long COVID.”

Participants will first be randomly assigned to receive either IVIG, ivabradine or a placebo. Participants will then be randomly assigned a second time to receive either coordinator-guided, non-drug care or what is considered the usual non-drug care for POTS following COVID-19, such as diet and lifestyle recommendations. RECOVER-AUTONOMIC is an adaptive clinical trial, meaning if additional potential interventions emerge, they can quickly be added and studied in the trial.

Researchers plan to enroll 380 total participants at 50 sites across the United States. Teams at the trial sites will recruit participants from their health systems and surrounding communities. The current list of sites for the trials can be found on [ClinicalTrials.gov](https://clinicaltrials.gov) (search: NCT06305793, NCT06305806 and NCT06305780) and additional sites will be added to this list as they begin enrolling participants.

Diversity among the trial participants is a high priority for RECOVER. To support diverse and inclusive representation, study sites are chosen based on geographic location, their connections to communities, and their track records for enrolling diverse research participants.

With the launch of the RECOVER-AUTONOMIC trials, RECOVER is currently testing seven

treatments across four clinical trials and continues to enroll participants. Those interested in learning more about RECOVER clinical trials should visit trials.recovercovid.org.

About RECOVER: The National Institutes of Health Researching COVID to Enhance Recovery (NIH RECOVER) Initiative brings together clinicians, scientists, caregivers, patients, and community members to understand, diagnose, and treat long COVID. RECOVER has created one of the largest and most diverse groups of long COVID study participants in the world. In addition, RECOVER clinical trials are testing potential interventions across five symptom focus areas. For more information, please visit recovercovid.org.

HHS Long COVID Coordination: This work is a part of the [National Research Action Plan](#), a broader government-wide effort in response to the [Presidential Memorandum](#) directing the Secretary for the Department of Health and Human Services to mount a full and effective response to long COVID. Led by Assistant Secretary for Health Admiral Rachel Levine, the Plan and its [companion Services and Supports for Longer-term Impacts of COVID-19](#) report lay the groundwork to advance progress in the prevention, diagnosis, treatment, and provision of services for individuals experiencing long COVID.

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