

Double-blind, Randomized, Placebo-controlled Study Evaluating Efficacy and Safety of IgPro20 in Post-COVID-19 POTS

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Provide written informed consent and be willing and, in the opinion of the investigator, able to adhere to all protocol requirements. 2. Males and females aged ≥ 18 at the time of providing written informed consent. 3. Diagnosis of post-COVID POTS, defined by both a preceding COVID-19 infection based on confirmed historical documentation and onset of POTS symptoms developing within 4 months after COVID-19 infection as defined per consensus criteria. 4. COMPASS-31 score of at least 40 at the Screening visit. 5. Positive confirmatory standardized standing test (ie, HR increase of ≥ 30 bpm \[≥ 40 bpm for participants aged 18 to 19 years\] within 10 minutes in the absence of orthostatic hypotension) at the Screening visit.

Exclusion Criteria:

1. Treatment with Immunoglobulin G (IgG) or plasmapheresis within 12 weeks before Screening 2. Symptoms and / or diagnosis of or receiving treatment for POTS before COVID-19 infection 3. Prior diagnosis of or receiving current treatment at Screening for the following conditions (unless onset was related to the inciting POTS-associated COVID-19 infection): certain neurologic, autoimmune, endocrine, cardiac, or other disorders, and pre-existing psychiatric disorders 4. Presence of active infections, including human immunodeficiency virus infection, hepatitis B, hepatitis C, active SARS-CoV-2 infection, or any uncontrolled systemic infection

Conditions & Interventions

Interventions:

BIOLOGICAL: IgPro20, BIOLOGICAL: Placebo

Conditions:

Post-COVID Postural Orthostatic Tachycardia Syndrome

Keywords:

POTS

More Information

Contact(s): Trial Registration Coordinator - clinicaltrials@csllbehrlng.com

Principal Investigator:

Phase: PHASE3

IRB

Number:

System ID: NCT06524739

Thank you for choosing StudyFinder. Please visit <http://studyfinder.cctr.vcu.edu> to find a Study which is right for you and contact ctrrecruit@vcu.edu if you have questions or need assistance.