

Study to Evaluate the Efficacy and Safety of Plitidepsin in Adults With Post-COVID-19 Condition (PCC)

NCT06766825

Status	RECRUITING
Phase	Phase 2
Sponsor	Fundación FLS de Lucha Contra el Sida, las Enfermedades Infecciosas y la Promoción de la Salud y la Ciencia
Enrollment	90 participants

Key Eligibility Criteria

Inclusion (6)

- Male or female individuals 18 years old or older.
- Evidence of SARS-CoV-2 infection at least 90 days prior to study recruitment, defined by either (a) nasopharyngeal SARS-CoV-2 nucleic acid test [polymerase chain reaction (PCR) or transcription mediated amplification (TMA)], (b) validated Nasopharyngeal Lateral Flow Assay rapid antigen test (RAT), or (c) or positive serology against SARS-CoV-2 N protein regardless vaccination status.
- or more symptoms of PCC affecting at least two organs, after 90 days from the onset of SARS-CoV2 infection and that last for at least 2 months and cannot be explained by an alternative diagnosis. Symptoms may be new onset following initial recovery from an acute COVID-19 episode or persist from the initial illness. Symptoms may also fluctuate or relapse over time.
- Unable to perform all usual duties/activities, defined as grades 3 or 4 in PCFS (Annex 3).
- Willing to comply with the requirements of the protocol and available for follow-up for the planned duration of the study.

... and 1 more (see full listing online)

Exclusion (16)

- Last SARS-CoV-2 vaccine dose during the previous 30 days.
- Patients with active uncontrolled infections.
- Patients infected by SARS-CoV-2 virus in the last 90 days prior to the screening visit.
- Patients receiving treatment with strong cytochrome P450 3A4 (CYP3A4) inhibitors or inducers (Annex 1) throughout plitidepsin treatment period and until 24-h washout period.
- Patients receiving chronic glucocorticoid therapy (high-dose corticosteroids [ie, 20 mg of prednisone daily or equivalent for e2 weeks])

... and 11 more (see full listing online)

Locations (1 total)

Hospital Universitari Germans Trias i Pujol, Badalona, Barcelona, Spain