

Optimisation of Antiviral Therapy in Immunocompromised COVID-19 Patients: a Randomized Factorial Controlled Strategy Trial

NCT05587894

Status	RECRUITING
Phase	Phase 2
Sponsor	ANRS, Emerging Infectious Diseases
Enrollment	256 participants

Key Eligibility Criteria

Inclusion (7)

- Laboratory confirmed SARS-CoV-2 infection by RT-PCR or positive antigenic test (commercialized assay)
 - Asymptomatic or mild to moderate COVID-19 (WHO progression scale ≤ 5 . Patients receiving oxygen therapy for reasons other than a pulmonary COVID-19 are eligible).
 - ≥ 16 years of age (for patients recruited in Italy and in Norway, ≥ 18 years of age);
 - Immunocompromised as defined by ≥ 1 risk factors for severe COVID-19 as assessed by the FOPH list (criteria 5: diseases/treatments leading to immune suppression) or other immunosuppression criteria such as Severe immunosuppression (e.g., HIV infection with CD4 + T cell count $< 350 / \mu\text{l}$) Neutropenia (< 1000 neutrophils / μl) ≥ 1 week Lymphocytopenia (< 200 lymphocytes/ μl) On dialysis treatment Hereditary immunodeficiencies Intake of drugs which suppress the immune system (e.g. glucocorticoids for a long time [an equivalent dose of prednisone > 20 mg/day > 3 months]), monoclonal antibodies, cytostatics, biological products, everolimus, mTOR inhibitors etc.) in the last 12 months Active cancer under cytostatics or targeted therapy known to be immunosuppressive (e.g., platinum salts, cyclophosphamide, anthracyclines, taxanes, 5-fluorouracil, gemcitabine, purine inhibitors, proteasome inhibitors) or associated with hematologic toxicity (neutropenia, lymphopenia), for example sunitinib, imatinib, regorafenib. Aggressive lymphomas (all types) Acute lymphatic leukemia Acute myeloid leukemia Acute promyelocytic leukemia T prolymphocytic leukemia Primary central nervous system lymphoma Stem cell transplantation Light chain amyloidosis Chronic lymphoid leukemia Multiple myeloma Sickle cell disease Bone marrow transplant Organ transplant Being on the waiting list for an organ transplant
 - Willing and able to comply with study requirements and restrictions as described in the informed consent form (ICF)
- ... and 2 more (see full listing online)

Exclusion (11)

- SARS-CoV-2 PCR ≥ 30 CT at screening
 - Hypersensitivity to study drugs (active substance(s) or excipients)
 - Body weight < 40 kg
 - AST and/or ALT > 5 times the upper limit
 - Cirrhosis Child-Pugh score C
- ... and 6 more (see full listing online)

Locations (18 total)

Saint-André Hospital, Bordeaux, Bordeaux, France
Pellegrin Hospital, Bordeaux, Bordeaux, France
Francois Mitterrand Hospital, Dijon, Dijon, France
... and 15 more locations

<https://clinicaltrials.gov/study/NCT05587894>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at ClinicalTrials.gov. Generated by ClinicalTrialsFinder.org.