

Short Summary

Immune response to infections and vaccines in dialysis patients in Ticino – KidneYimmune

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Introduction

Currently, more than 4,400 end stage kidney disease (ESKD) patients undergo dialysis in Switzerland. In this population, and more generally in chronic kidney disease (CKD) patients, the innate and the adaptive immune systems are dysregulated, leading to an increased risk of infections and reduced response to vaccines. Bacterial and viral infections are the main cause of morbidity and the second cause of death following cardiovascular events in this population. The novel SARS-CoV-2 coronavirus pandemic (COVID-19) has posed a new infectious threat for patients with CKD, which is associated with an enhanced risk of severe disease manifestation. In fact, the estimated mortality rate of dialysis patients in the nephrology units of Ticino is estimated to be 5.3%, which is about 3 times higher than that in the Swiss HD cohort¹. Furthermore, the influenza vaccination in ESKD patients has been shown to induce an insufficient immune response compared to the age-matched general population. Taken together, these data suggest that ESKD patients are particularly vulnerable to infectious diseases, and more in-depth studies are needed to understand the basis of their immune response disorder to infections and vaccines.

Aim of the study

The first aim of the study is to perform a detailed characterization of the antibody and cellular response to viral and bacterial pathogens, as well as to vaccines in patients with ESKD treated with hemo- or peritoneal-dialysis. The second aim is to collect data on seroprevalence and rate of seroconversion to SARS-CoV-2 in the ESKD cohort. The third aim is to isolate antibodies capable of neutralizing life-threatening pathogens that may cause infections during the follow-up period. Overall, this study could provide important data for deciding whether dialytic patients would be eligible for active immunoprophylaxis when a vaccine for SARS-CoV-2 is available, or would benefit more from a passive immunotherapy with monoclonal antibodies.

Intervention

The target population of the study is represented by the patients in dialysis (HD or PD), recruited from all of the public nephrology units of Ticino (EOC). Around 230 patients can be included. The overall project duration is 12 months (September 2020 - August 2021). The study comes under Category A, as minimal risks and burdens may be associated with surveys and observations, peripheral venous blood sampling, and bodily substances may be collected without invasive interventions (blood sampling from HD procedure and peritoneal lavage fluid discarded after PD). Sampling analysis will be performed by Humabs BioMed, Bellinzona, which has developed several immunological assays to study the immune response using plasma and peripheral blood mononuclear cells (PBMCs). These innovative and highly specific techniques have already been used successfully in the “CoV-2-Ig” study in collaboration with EOC and the Institute for Research in Biomedicine (IRB), Bellinzona, which aimed to determine the seroprevalence of SARS-CoV-2 antibodies in the healthcare workers population in Ticino.

¹source: Ufficio del medico cantonale <https://www4.ti.ch/dss/dsp/covid19/home/> and The Swiss Renal Registry and Quality Assessment