



Jan 23, 2021

# Role and effects of zinc supplementation in HIV-infected patients with immunovirological discordance: A randomized, double blind, case control study.

PLOS One

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## ABSTRACT

It has been estimated that between 15% and 18% of patients who start antiretroviral therapy (ART) do not achieve a successful immune recovery despite complete virological suppression. In the literature this phenomenon is known as poor immune recovery or immunovirological discordance (IVD). Zinc has an immunomodulatory role associated with T lymphocytes and its supplementation could enhance immune recovery. **OBJECTIVE:** to determine if zinc supplementation on IVD patients prevents immune failure after 12 months of supplementation. Secondary objectives were to determine serum zinc levels in HIV patients with and without IVD and the frequency of hypozincemia in discordant patients. **METHOD:** we reviewed the historical record of patients under care at Arriarán Foundation. Following inclusion criteria were defined: 1) age  $\geq 18$  years, 2) standard ART (three effective drugs) for at least 18 months, 3) virologically suppressed for 12 months, 3) persistence of CD4 count  $\leq 200$  cells/mm<sup>3</sup> and/or increase  $\leq 80$  cells/mm<sup>3</sup> after one year of viral undetectability. A control group was assigned paired 1:1 by sex, age ( $\pm 2$  years) that did achieved an increase of CD4  $> 350$  cells/mm<sup>3</sup>. In both groups plasma zinc levels were determined. In a later phase, patients with IVD were randomized to receive zinc (15 mg daily) versus placebo. Patients were followed for 12 months with CD4 count, viral load and zinc levels determinations every 4-6 months. **RESULTS:** a total of 80 patients, 40 patients with IVD criteria and 40 controls were included. 92.5% were men, and age average was 47.5 years. The median baseline CD4 was 189 cells/mm<sup>3</sup> (71-258) in the cases vs. 552.5 cells/mm<sup>3</sup> (317-400) in the control group with a total increase at the end of the study of 34 cell/mm<sup>3</sup> and 30 cell/mm<sup>3</sup> respectively. There was no difference in baseline plasma zinc levels between both groups (81.7 + 18.1 in cases versus 86.2 + 11.0 in controls). In the 40 patients with IVD, the median absolute increase in CD4 after annual zinc supplementation was 31.5 cells/mm<sup>3</sup> in the treated group versus 50 cells/mm<sup>3</sup> in the placebo group, this difference being statistically not significant ( $p = 0.382$ ). **CONCLUSIONS:** Patients with IVD have plasma zinc levels similar to those who achieve adequate immune recovery. Zinc supplementation in IVD patients showed a statistically non-significant increase in CD4 levels between cases and controls. The results warrant a comparative study with a larger number of patients.

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## DOI

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## PROTOCOL CITATION

Macarena Silva, Carmen G Montes, Andrea Canals, Maria J Mackenna, Marcelo Wolff 2021. Role and effects of zinc supplementation in HIV-infected patients with immunovirological discordance: A randomized, double blind, case control study.. **protocols.io**  
<https://dx.doi.org/10.17504/protocols.io.bpqimmue>

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KEYWORDS

Zinc, virological discordance, immunovirological discordance, immune failure, HIV

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CREATED

Nov 14, 2020

LAST MODIFIED

Jan 23, 2021

PROTOCOL INTEGER ID

44522