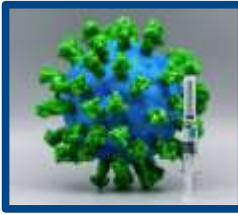


The induction of *de novo* autoimmune biomarkers production in healthcare professionals vaccinated with BNT162b2

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INTRODUCTION



The vaccine BNT162b2 was the first one to be approved and the first mRNA-based vaccine ever. Some vaccines are known to induce autoinflammatory mechanisms, most of those are mild and transient and only a minor part are pathogenic. To date, the literature has reported the existence of a link between autoimmunity and COVID-19. The aim of this study was to evaluate whether subjects vaccinated with BNT162b2, initially negative to autoimmune biomarkers, will show at 3 months after the second dose of vaccine, a *de novo* production of autoantibodies.

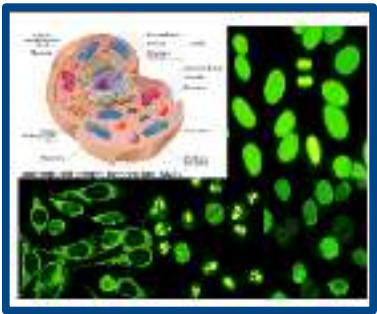
METHODS



Blood samples of 155 healthcare professionals (HCPs) of our hospital (114 females and 41 males, age range 20-66 years, median age 46) vaccinated with COVID-19 mRNA BNT162b2 (Pfizer) were collected before (T0) and 3 months after the administration of the two doses of the vaccine (T1). All samples were analysed for the presence of a) antinuclear antibodies (ANA) and anti-smooth muscle antibodies (ASMA) (Indirect Immunofluorescence [IIF], Euroimmun); b) anti-myeloperoxidase (anti-MPO), anti-proteinase 3 (anti-PR3) and anti-citrullinated peptide antibodies (anti-CCP) ([FEIA], Thermo Fisher Scientific); c) anti-phospholipid antibodies (anticardiolipin [aCL], anti-beta-2- glycoprotein I [anti-β-2GPI] (Chemiluminescence, Werfen). Clinical data were collected using the REDCap software (REDCap version 10.2.3©2020 Vanderbilt University).

RESULTS

Fifty (32,3%) out of 155 HCPs, presented ANA and 15 (9,7%) ASMA at T0. In contrast at T1, 53/137 HCPs, were positive for ANA (38,7%) and 21 (15,3%) for ASMA at T1.. Most importantly, 9 HCPs that were negative at T0 for ANA and 10 negatives for ASMA, display a newly generated positivity at T1. Nine HCPs had high positive levels of β-2GPI IgG and aCL at all time points and the values did not significantly change after vaccination.



CONCLUSIONS

Our preliminary results regarding the BNT162b2 vaccine effects on the development of potential autoimmune events in healthy individuals revealed an induction of autoinflammatory mechanisms in a small percentage of HCPs, developing a *de novo* autoantibodies production after vaccination.