

Cellular immune responses following a fractional versus standard dose of COVID-19 vaccine (Pfizer-BioNTech [BNT162b2]) in Mongolian adults: a randomized control trial

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Background: Fractional COVID-19 vaccine boosters have been shown to provide similar levels of immunogenicity and effectiveness compared to standard doses. The benefits of fractional dosing include reducing cost and vaccine supply issues, particularly for lower-middle income countries that currently have low vaccine coverage. This project evaluated the immunogenicity of a fractional (15mg) versus standard (30mg) dose of Pfizer-BioNTech (BNT162b2) following two priming doses of BBIBP-CorV, ChAdOx1 nCoV-19, or Gam-COVID-Vac in Mongolian adults >18 years of age. Here we report on the cellular immune responses in this study.

Methods: There were 601 participants recruited into this study. Blood samples were collected before (day 0) and 28-days after booster vaccination. Antibody responses were measured to ancestral (Wuhan-Hu-1) SARS-CoV-2 spike protein IgG (Euroimmun, ESL BioSciences) and neutralising (Wuhan and Omicron BA.1) antibodies by the surrogate virus neutralisation (sVNT) test (Genscript). Cell-mediated immunity was measured by QuantiFERON SARS-CoV-2 IFN- γ release assay (Qiagen) in a subset of participants (N=254). Antigen-specific T cell responses using PBMCs measured by flow cytometry are ongoing.

Results: Following the booster dose, irrespective of fractional or standard dose arms for each priming group there was a significant increase in Omicron (BA.1) neutralizing antibodies ($p<0.0001$) and for Wuhan Ag1-Nil and Ag2-Nil IFN- γ release (IU/mL) (BBIBP-CorV $p<0.0001$, ChAdOx1 nCoV-19 $p=0.005$, Gam-COVID-Vac $p=0.036$), with no significant differences observed at day 28 amongst different priming vaccine groups.

Conclusion: The fractional dose (15mg) of Pfizer-BioNTech was found to generate similar functional antibody and cellular immunity to a standard dose schedule. This study has implications for use of fractional dose booster strategies to improve COVID-19 vaccine coverage and protection globally.

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