Safety and immunogenicity of the SARS-CoV-2 BNT162b1 mRNA vaccine in younger and older Chinese adults: a randomized, placebo-controlled, double-blind phase 1 study

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Abstract:

An effective vaccine is needed to end the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic. Here, we assess the preliminary safety, tolerability and immunogenicity data from an ongoing single-center (in Jiangsu province, China), parallel-group, double-blind phase 1 trial of the vaccine candidate BNT162b1 in 144 healthy SARS-CoV-2-naive Chinese participants. These participants are randomized 1:1:1 to receive prime and boost vaccinations of 10 µg or 30 µg BNT162b1 or placebo, given 21d apart, with equal allocation of younger (aged 18 - 55 years) and older adults (aged 65 - 85 years) to each treatment group (ChiCTR2000034825). BNT162b1 encodes the SARS-CoV-2 spike glycoprotein receptor-binding domain (RBD) and is one of several messenger RNAbased vaccine candidates under clinical investigation. Local reactions and systemic events were generally dose dependent, transient and mild to moderate. Fever was the only grade 3 adverse event. BNT162b1 induced robust interferon- γ T cell responses to a peptide pool including the RBD in both younger and older Chinese adults, and geometric mean neutralizing titers reached 2.1-fold (for younger participants) and 1.3-fold (for the older participants) that of a panel of COVID-19 convalescent human sera obtained at least 14d after positive SARS-CoV-2 polymerase chain reaction test. In summary, BNT162b1 has an acceptable safety profile and produces high levels of humoral and Tcell responses in an Asian population.