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 21 d 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 RNA-based 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 14 d after positive SARS-CoV-2 polymerase chain reaction test. In summary, BNT162b1 has an acceptable safety profile and produces high levels of humoral and T cell responses in an Asian population.