Estimation of Neutralizing Antibodies among Pizer/BioNTech (BNT162b2) Vaccine Recipients in Benghazi, Libya.

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Introduction

Natural infection and vaccination are the two ways in which immunity to SARS-CoV-2 can be acquired.

Regarding adaptive immunity to SARS-CoV-2, both T cells, and B cell producing neutralizing antibodies (nAbs) contribute some degree of clinical protection.

The important role of neutralizing antibodies in protection of SARS-CoV-2 has been demonstrated by the results of passive transfer of nAbs to non-RBD epitopes on the spike (S) protein that was able to prevent severe SARS-CoV-2 infection in animal models.

Regeneron has reported similar data in humans (passive vaccination).

Convalescent plasma transformation has also shown an ability to dramatically improve clinical symptoms.

Pizer/BioNTech (BNT162b2), is a lipid nanoparticle-formulated nucleoside-modified mRNA that encodes the viral spike glycoprotein of SARS-CoV-2.

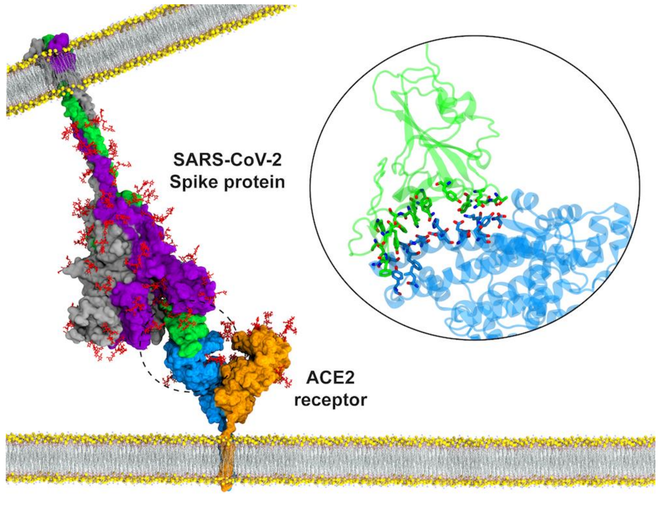

Figure 1: Atomic model for binding of the SARS-CoV-2 S protein to the ACE2 receptor on the host cell membrane.
[Credit: University of California, Berkeley; Istanbul Technical University]

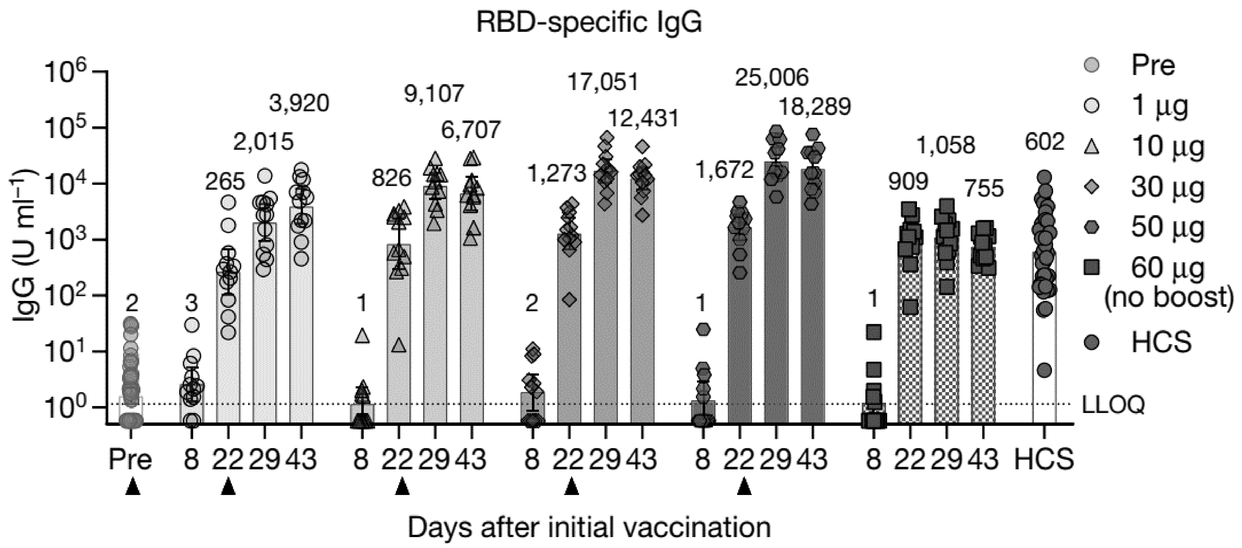

Figure 2: BNT162b1-induced IgG concentrations.

Methodology

Ethical approval was obtained by ethical committee at LIMU and informed consent of patients will be taken.

A descriptive, cross-sectional, community-based study will be conducted in Benghazi, Libya involving all vaccinated people since June 2021 with exclusion of all previously SARS-CoV-2 infected individuals, to estimate the efficacy of Pizer/BioNTech (BNT162b2) using neutralizing antibodies levels.

10 item questionnaire will be used to collect personal information, social demographic and previous infection data.

From 100 participant 5 ml of venous blood will be collected in EDTA blood tubes, samples then will be centrifuged at 3000 round per minute then plasma will be gathered and analyzed for neutralizing antibodies level using automated chemiluminescent immunoassay (CLIA).

Statistic analysis will be done using SPSS version 24.

Expected results and discussion

According to the clinical evidence of neutralizing antibodies it has been founded that the higher the titter the higher the protection, we expect that knowing the neutralizing antibodies levels in the participants will allow us to estimate the protective neutralization level, as well as the efficacy of the vaccines can be measured according to the same concept, moreover we will provide more information for vaccine receivers and other researchers.

Study 1

- A study conducted in Germany with 60 participants revealed that immunized participants showed a strong, vaccine-induced antibody response where geometric mean concentrations of RBD-binding IgG had increased in a dose-dependent manner. **(Fig.2)**

Note: 60 µg dose-level cohort, which received a priming dose only, the RBD-binding IgG GMC was 755 U ml−1 by day 43, indicating that a boosting dose is necessary to increase antibody concentrations.

Study 2:

- in a placebo-controlled efficacy trial conducted at 152 sites worldwide, where 43,548 individuals participate, a two-dose regimen of BNT162b2 30 µg per dose given 21 days apart was found to be safe and 95% effective against Covid-19 .

In Libya 234,000 doses of Pfizer Coronavirus vaccine arrived on 21st of November 2021.

probably due to the country's current political situation and socioeconomic status of the majority of Libyan citizens, vaccination program wasn't as organized as in the trails that has been held in other countries with a relatively strict program, and the opportunity for Libyan citizens to get all the priming and booster doses was lesser compared to other individuals receiving the same vaccine in other places, all that most likely will affect the degree of protection that suppose to be provided and that might affect the results we are expecting depending upon the previous studies.

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