

Plain Language Summary of the PICOB00 Study: Early Results of a 2nd Booster in 50-69 Year Olds Primed with Astra Zeneca

Overview of the PICOB00 Study

The **P**latform Trial **I**n **C**OVID-19 Priming and **B**OOsting (**PICOB00**) is a clinical trial that explores different COVID-19 vaccination strategies. This trial is being run across 3 locations in Australia: Perth, Adelaide and Launceston.

Summary of Results

This summary shares the early results from the study involving people aged 50 to 69 years old. This group received two AstraZeneca vaccines initially, and then a 1st booster outside of the study. When joining this study, they were randomly given one of three possible COVID-19 vaccines as a 2nd booster. We looked at the effects of this 2nd booster over 84 days.

We looked at the impacts of the booster vaccines on the immune system and checked for any side effects or safety issues. The three booster shots tested were the original Pfizer (BNT162b2), Moderna (mRNA-1273), and Novavax (NVX-CoV2373) vaccines.

Who Took Part

A total of 743 people joined the study between March 2022 and August 2023, with 155 people in the 50-69 age group. Approximately 75% were female and 25% were male. Overall, 15% of participants had a prior COVID-19 infection before they joined the study.

What We Found

Building the Body's Defence (Immune Response)

- The vaccines teach your body to recognise and fight the COVID-19 virus by making special defenders called antibodies. These are proteins the body uses to fight infections.
- We measured antibody levels in each person to see how well the vaccines work over time.
- People who got the mRNA vaccines (Pfizer and Moderna) had more antibodies after 28 days compared to those who got the Novavax vaccine. But, by day 84, the number of antibodies had decreased
- It's not clear how important the higher antibody levels are from the Pfizer and Moderna vaccines.

Fighting New Virus Types (Immune Response)

- We also checked how well these vaccines stop the COVID-19 virus as it changed and evolved.
- We tested the antibodies from people's blood to see if they could stop new versions of the virus from infecting cells in lab experiments.
- The original vaccines were better at destroying the original virus strain compared to newer variants like Omicron BA.5 and XBB.1.5.

- This shows the importance of updating vaccines to better fight these new virus types. The current vaccines available for use in Australia do target newer circulating variants.

Side Effects and Safety

- Most side effects were mild, like sore arms, headaches, and feeling tired.
- Severe reactions occurred in less than 4% of people.
- This indicates that these vaccines were safe for most people in this group.

Getting COVID-19 After the Vaccine

- Some people caught COVID-19 after getting their booster shot, but none were serious enough to need to go to the hospital.
- This suggests that vaccines help stop serious illness from COVID-19 infection.

Key Takeaways

- **mRNA Vaccines Stand Out:** The Pfizer and Moderna vaccines provided a higher antibody response against COVID-19, compared to the Novavax vaccine. The importance of the higher antibody levels is unknown.
- **Generally Safe with Mild Side Effects:** The vaccines were easy to tolerate with only mild side effects.
- **Updating Vaccines for New Strains:** As the virus changes, it's important to keep updating the vaccines to fight off new strains better.
- **Significance for Public Health:** These results support the use of booster shots and highlight the importance of updating vaccines to combat new COVID-19 strains. This is why older vaccines have been discontinued and replaced with new versions that better target the latest strains like the XBB.1.5 vaccines, which are currently in use.

Acknowledgements

Thank you to the large team of researchers and participants for making this study possible. This study was funded by the Medical Research Future Fund (2014690) and Snow Foundation.

Authorship and Reference

Summary authored by George Salama. Original full report: McLeod C, et al. (2024). *The Platform Trial In COVID-19 Priming and BOOsting (PICOBOO): the immunogenicity, reactogenicity, and safety of different COVID-19 vaccinations administered as a second booster (fourth dose) in AZD1222 primed individuals aged 50-<70 years old.*