Te Niwha

Research Project Impact Case Study

Randomised controlled trial evaluating immunogenicity and reactogenicity of subcutaneous versus intramuscular COVID-19 vaccination

COVID-19 Needle Length Study

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Introduction

COVID-19 vaccines are intended for injection into the deltoid muscle in the arm. However, previous research identified standard 25mm needles are inadequate to ensure intramuscular injection in 45% of adults with obesity. Currently, vaccination guidelines provide non-specific advice about needle selection, and less than 2% of COVID-19 vaccinations in Aotearoa being delivered with a longer 38mm needle. Therefore, a significant population in Aotearoa are inadvertently receiving their COVID-19 vaccines into the subcutaneous tissue. For some vaccines, subcutaneous administration can increase the risk of injection site reactions and reduce immune response. However, it is currently unknown if delivery location for COVID-19 vaccines influences the immune response or the severity of adverse reactions following vaccination.

This randomised controlled trial compares immunogenicity and reactogenicity of subcutaneous versus intramuscular injection of the COVID-19 vaccine. In total, 400 adults will be recruited from community vaccinating pharmacies in Aotearoa to receive the COVID-19 booster via a 12.7mm or 38mm needle and are followed up over 15 weeks.

Research partners include community pharmacies across Aotearoa, Pacific Health Services Hutt Valley and Mareroa Marae Health Clinic. This project develops pharmacist research capacity, ensuring the network of embedded community pharmacy research hubs across A/NZ can rapidly and efficiently respond when a new infectious disease threat emerges.

Results

Recruitment was completed in August 2025, with full enrolment of 400 participants. The final day-105 follow-up visit was completed in November 2025. The participant database was locked in December 2025, and reactogenicity analyses have been completed.

Immunogenicity analyses are currently underway and are expected to be completed in Q1 2026. Throughout the study, community pharmacists and students were actively involved in study delivery, participant follow-up, and data collection, contributing to the development of sustainable clinical trial capability within community pharmacy settings.

Impact

This study will provide the first high-quality randomised evidence on whether intramuscular delivery of COVID-19 vaccines is necessary to achieve optimal immune responses, and whether inadvertent subcutaneous administration alters reactogenicity. These findings will directly inform vaccine delivery practices, particularly for individuals with higher body mass, helping ensure vaccines are administered safely and effectively for all body types.

The results have clear implications for public health policy and vaccination guidelines. Key stakeholders, including the Immunisation Advisory Centre, Health New Zealand, the Māori Health Authority, and the Ministry of Health, are being kept informed of study progress, given the potential for findings to inform national and international immunisation guidance.

Beyond the immediate scientific outcomes, this project has established durable research infrastructure and strengthened a national network of pharmacist-led community research hubs. This platform is already being leveraged to design future randomised controlled trials, including a planned study comparing subcutaneous versus intramuscular delivery of influenza vaccines, for which funding is being actively sought.

By combining rigorous clinical science with community-based delivery, this research demonstrates how embedded pharmacy research networks can generate timely, policy-relevant evidence and enhance Aotearoa's preparedness for future infectious disease responses.