Com-COV vaccine mix-and-match study expands to 12- to 16-year-olds

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Researchers running the University of Oxford-led Com-COV program have launched a new study of COVID-19 vaccination schedules in young people aged 12 to 16.

Backed through funding from the Vaccines Taskforce and National

Institute for Health Research (NIHR) and run across four NIHR-supported sites by the National Immunisation Schedule Evaluation Consortium, the Com-COV 3 trial will seek to recruit 360 volunteers.

Professor Matthew Snape, Associate Professor in Pediatrics and Vaccinology at the University of Oxford, and Chief Investigator on the trial, said: "This study will provide vital information on the range of options for immunizing teenagers against COVID-19 in the UK.

"As well as looking at the standard two full doses of the Pfizer vaccine, we will look at how well volunteers respond when their second dose of Pfizer is half that of the first dose, or if different vaccines are used altogether, such as the vaccines manufactured by Moderna or Novavax. This will provide the JCVI with information crucial to informing their advice about immunizing teenagers in the UK."

Participants can either receive two COVID-19 vaccine doses in the study, in which case their first dose will be the Pfizer COVID-19 vaccine. Alternatively, those who have already received a dose of the Pfizer COVID-19 vaccine through the NHS can be enrolled at the time of their second dose.

All participants will be randomly allocated at the time of the second dose to receive either a full dose or half dose of the Pfizer-BioNTech vaccine, a full dose of the Novavax vaccine or a half dose of the Moderna vaccine.

Professor Matthew Snape said: "This is the latest in series of studies such as COMCOV and COV-Boost that have looked at ways the different COVID-19 vaccines available in the UK can be used to generate the best and most durable immune response, in as safe a manner as possible."

The study is single-blind and randomized, meaning participants will not

know what second dose vaccine they are receiving. Researchers will assess reactogenicity (any side effects) and immune system responses to these new combinations of vaccines.

Professor Andrew Ustianowski, NIHR Clinical Lead for COVID-19 Vaccination Program and Joint National Infection Specialty Lead, said: "It is important to establish the most effective vaccine doses for different population groups, and this latest study will help develop our understanding of immune responses for young people once vaccinated against COVID-19.

"We continue to see valuable contributions from volunteers across COVID-19 vaccine research across the UK to help us identify the best vaccine schedules, and I hope we see similar levels of engagement with the Com-Cov 3 study."

The study hopes to report initial results by December—if the results are promising, regulators MHRA and JCVI would formally assess the safety and efficacy of any new vaccination process before advising whether it is rolled out to patients.

All those who are interested can register via the study website comcovstudy.org.uk

A brief Com-COV timeline

The University of Oxford is leading the Com-COV 3 study, run by the National Immunisation Schedule Evaluation Consortium (NISEC) and backed by £2.8 million of government funding from the Vaccines Taskforce.

In May, researchers reported preliminary Com-COV data revealing more frequent mild to moderate reactions in mixed schedules compared to

standard schedules, however, these were short-lived in duration. In June, they further reported that 'mixed' schedules involving Pfizer-BioNTech and Oxford-AstraZeneca induced high concentrations of antibodies against the SARS-CoV2 spike IgG protein when doses were administered four weeks apart.

In April, the researchers expanded the program to include the Moderna and Novavax vaccines in a new study.

Provided by University of Oxford