

The Combining Influenza and COVID-19 Vaccination (ComFluCOV) study explained

What was the purpose of this research study?

The Combining Influenza and COVID-19 Vaccination (ComFluCOV) study looked to establish the safety of co-administering the most widely used COVID-19 and influenza vaccines in the UK and describe the expected side effects and immune responses to the vaccines when they are given together. This information is needed to help to work out how best to deliver COVID-19 vaccines during the overlap with the influenza vaccine season.

What are the vaccines used for?

The vaccines used in this study protect against the influenza viruses that causes 'flu', and the coronavirus, SARS-CoV2, that causes COVID-19 infection.

The COVID-19 vaccines protect against severe COVID-19 infection that can lead to death and is more common in older people, those with underlying medical conditions and some ethnic groups.

Older adults and those with underlying medical conditions are also more at risk of severe influenza infection. In the UK influenza causes over 1000 deaths each year. This is why an effective vaccine programme against both of these diseases is so important. If both vaccines can be given together it will mean fewer appointments for those receiving the vaccines and will prevent delays in getting vaccinated against one of the infections.

Which vaccines were used in this study?

The COVID-19 vaccines being used in this study were:

- ChAdOx1 nCoV-19 (Oxford/AstraZeneca)
- BNT162b2 (Pfizer/BioNTech)

Participants received the same COVID-19 vaccine as they did for their first dose as part of the UK mass vaccination programme. Neither COVID-19 vaccine contains the SARS-CoV-2 coronavirus and therefore cannot give you COVID-19.

The three flu vaccines in this study were:

- Flucelvax QIV (recommended for people aged under 65 years old)
- FluBlok QIVr (recommended for people aged under 65 years old)
- FluAd (MF59) (recommended for people aged over 65 years old)

Participants received the flu vaccine recommended for their age group from the 2020/21 season.

For those aged under 65 years old, some hospitals used Flucelvax and others used Flublok.

Who took part in the study?

A total of 679 volunteers took part in this study, all aged 18 and over. In order to take part in the study participants had received their first dose of either the Pfizer/BioNTech COVID-19 vaccine or the Oxford/AstraZeneca COVID-19 vaccine and were due to get their second dose.

What did the study involve?

Participants attended three study appointments at their nearest participating hospital and there was a gap of about three weeks between each study visit.

Participants were allocated into one of two groups, at random by a computer:

- A group who received their second dose of the COVID-19 vaccine and the flu vaccine at their first study visit, then a saline injection (placebo) at their second visit
- A group who received their second dose of the COVID-19 vaccine and a saline injection (placebo) at their first visit and then the flu vaccine at their second visit.

No vaccines were given at the third visit, but blood and saliva samples were taken at each study visit to look at the immune responses to the vaccines.

What happened after the vaccinations

Participants completed an online diary for seven days the first and second appointment to record any side effects. Any other problems such as visits to the doctor or dentist or serious medical illness were also reported to the study team to assess the safety of vaccination.

What do the results of the study show?

The ComFluCOV study found that it is safe for people to receive a flu vaccine at the same time as a COVID-19 vaccine. Reported side effects were mainly mild to moderate, and there were no negative impacts on the immune response produced by either vaccine when both were given in the same day, in opposite arms.

The most common side effects were pain around the injection site and fatigue. With some combinations there was an increase in the number of people who reported at least one side effect when both COVID-19 and flu vaccine were given together, but the reactions were mostly mild or moderate so the increase was considered acceptable.

97% of participants would be willing to have two vaccines at the same appointment in the future, with only 3% of those who were employed needing to take time off work due to vaccine side effects.

What will happen as a result of this study?



The results from this study have been presented to the Joint Committee on Vaccination and Immunisation (JCVI) and the Medicines and Healthcare products Regulatory Agency (MHRA), for them to consider.

The MHRA has updated their guidance for healthcare professionals for both the [Oxford/AstraZeneca](#) and [Pfizer/BioNTech](#) COVID-19 vaccines (sections 4.5 on both documents) to reflect that the data from the ComFluCOV study shows that the antibody responses when administering these COVID-19 vaccines with influenza vaccines at the same appointment, in opposite arms, are unaffected and that the side effects experienced are acceptable. The MHRA has needed to rely on these data in advance of them being publicly available, including to Pfizer/BioNTech and AstraZeneca, but is satisfied as to the arrangements for its expected publication, and will update its guidance once the data are published.

Information presented to the JCVI from the ComFluCOV trial indicates that co-administration of the influenza and COVID-19 vaccines is generally well tolerated with no reduction in immune response to either vaccine. Therefore, the [JCVI](#) has advised that, where operationally expedient, COVID-19 and influenza vaccines may be co-administered