



## **The Combining Influenza and COVID-19 Vaccination (ComFluCOV) Study explained**

### ***What is the purpose of this research study?***

There are now vaccines that have been approved to protect against COVID-19 in the UK. The duration of protection of these COVID-19 vaccines is unknown but further booster doses may be required to give continued protection.

With the challenges of immunising large numbers of people against COVID-19 and the need to continue the seasonal influenza (flu) vaccination schedule, it would be preferable if we could give people both their COVID-19 booster and flu vaccine at the same appointment. This would mean receiving two vaccines on the same day, one in each arm. It would also mean fewer appointments for those who need both vaccines and would reduce the burden on the NHS.

Therefore, the purpose of the ComFluCOV study is to see what side effects, such as fever and tiredness, people get when they are given their second dose of the COVID-19 vaccine at the same time as the currently recommended flu vaccine. We will also look at people's immune responses to both vaccines when given together.

### ***What are the vaccines used for?***

The vaccines being used in this study are vaccines against flu and the coronavirus SARS-CoV2 that causes the disease COVID-19. Common symptoms of COVID-19 include fever, tiredness, dry cough, and changes to taste and smell.

Whilst most infected people have no or mild symptoms and recover without needing special treatment, some people develop severe symptoms and become critically ill. Older people and those with underlying medical conditions are more likely to develop serious illness and people in some ethnic groups (Black and Asian) might be at a greater risk of severe illness.

Symptoms of flu include fever, body aches, fatigue and a dry cough. Most people will have mild symptoms and recover, but certain groups are at higher risk of severe disease and complications such as older people and those with underlying medical conditions. In the UK, people in higher risk groups are invited to receive a flu vaccine every winter. This is why an effective vaccine programme against both of these diseases is so important.

### ***Which vaccines are being used in this study?***

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

- ChadOx1 nCoV-19 (Oxford/AstraZeneca)
- BNT162b2 (Pfizer/BioNTech)

You would receive the same COVID-19 vaccine as you did for your 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 are:

- 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)

You would receive the flu vaccine recommended for your age group from the 2020/21 season.

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

### ***Who can take part in the study?***

Adults that are aged 18 and over are able to take part in this study. In order to take part in the study participants must have received their first dose of either the Pfizer/BioNTech COVID-19 vaccine or the Oxford/AstraZeneca COVID-19 vaccine and be awaiting their second dose.

There may be some people who are not eligible to take part. This will be determined from answers to the questions in the online screening questionnaire and a discussion with the local research team.

### ***What does the study involve?***

In total this study will enrol 756 participants.

Interested volunteers should complete the online screening questionnaire [insert link]. If you are eligible to take part you will be called by the research team and invited to join the study.

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

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

- One group will receive their second dose of COVID-19 vaccine and the flu vaccine at Visit 1 and then a saline injection (placebo) at Visit 2.
- The other group will receive their second dose of COVID-19 vaccine and a saline injection (placebo) at Visit 1 and then the flu vaccine at Visit 2.

No vaccines will be given at the third visit, but a blood and saliva sample will be taken at each study visit to look at the immune responses to the vaccines.

### ***What happens after the vaccinations***

Participants will need to complete an online diary for seven days after Visit 1 and for seven days after Visit 2. . Participants will also be asked to record any unplanned visits to the doctor/dentist and any serious medical illnesses or hospital visits. Participants will receive a



daily email reminder with a link to record any relevant information. This will then be reviewed at the following visit.

***What are the risks of taking part in the study?***

Having both the COVID-19 and influenza vaccine on the same day may mean more side effects, but we do not know this for certain and is one of the reasons why we're doing this study. We will be asking those who take part to let us know about side effects on a daily basis and will get in touch if there are any concerns.

***When will results be available?***

The primary outcome of this study should be available summer 2021, with a full analysis to follow.