

Participant Study Summary Leaflet

Combining Recombinant Herpes Zoster and Influenza or COVID-19 Vaccination (ZosterFluCOV) Study

We are recruiting adults aged 50 and over to a study which is looking at the safety and immune response of a vaccine against shingles (herpes zoster) given at the same time as influenza (flu) vaccine or COVID-19 vaccine.

This is a summary of the study. For more information please scan the QR code on the final page or go to the study website zosterfluCoV.blogs.bristol.ac.uk.

Why are we doing this study?

We want to know whether receiving a shingles vaccine at the same time as either a flu or COVID-19 vaccine is safe and works as well compared to when the shingles vaccine is given alone. In the UK, a shingles vaccine is offered to people when they reach 70. Flu and COVID-19 vaccines are also offered to people in this age group. If we could give the shingles vaccine at the same time as either the flu or COVID-19 vaccine it may make it easier for people, and for GPs, as fewer appointments would be needed.

Who can take part in the study?

We are looking for volunteers aged 50 years and over. In order to take part in the study you must not have received a shingles vaccine within 5 years of your enrolment in the study. It is also important that you have received your initial COVID-19 vaccinations (usually two doses).

Taking part is voluntary

It is up to you to decide whether to take part. If you do decide to take part, you will need to read this information leaflet in full and will be asked to sign a consent form. You are free to withdraw from the study at any time and without giving a reason.

What are the benefits?

The information gained from the study will help us to determine whether it is safe and effective to give the shingles vaccine at the same time as the flu vaccine or the COVID-19 vaccine.

What are the risks?

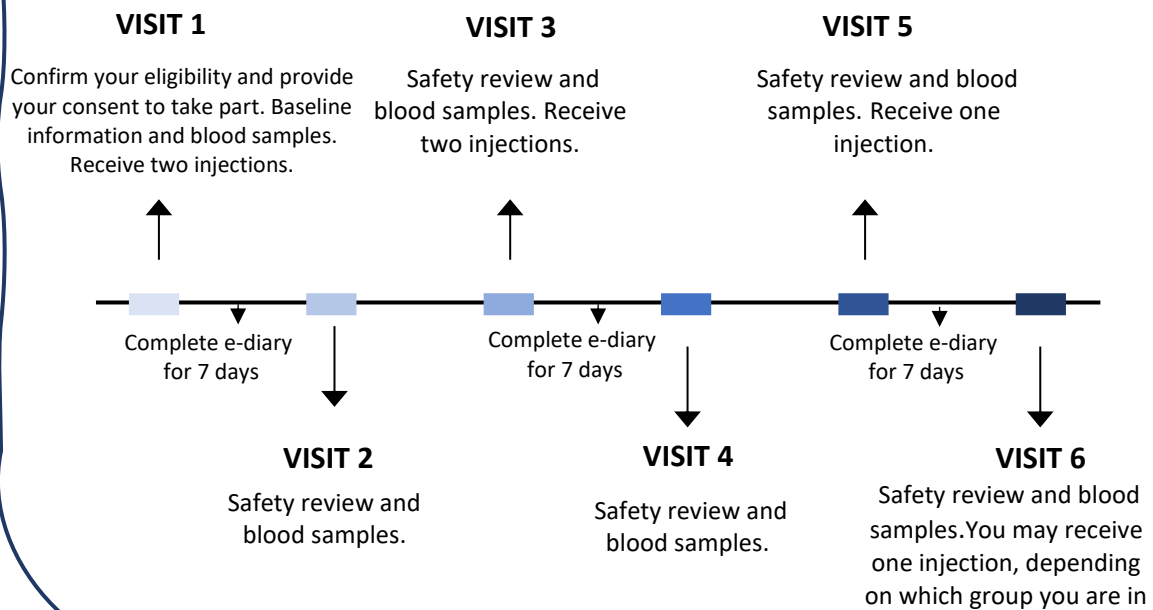
The vaccines used in this study are used as part of standard care and so have been well tested, however, people often experience side effects after receiving a vaccination and a part of the study is to investigate the side effects experienced as a result of receiving these vaccines at the same time.

As part of this study you may be asked to provide a blood sample at each study visit, this can cause discomfort.

What would taking part involve?

- ❖ You will be required to attend 6 study visits over a period of 20 weeks.
- ❖ You will be randomly allocated to receive a COVID-19 or flu vaccine or saline placebo together with your first or second dose of the shingles vaccine.
- ❖ You will not be told which vaccines you are getting together in case knowing this would affect the results of the study.
- ❖ The vaccines used in the study are all licensed and are given routinely by GPs.
- ❖ You may be required to provide blood samples at your study visit. In some groups, some people won't need blood samples at some time points. Your bloods will be used to test immune responses to the vaccines.
- ❖ You may be asked if you are willing to talk to a researcher about your vaccinations and experiences, 3-4 months after you join the study. This interview is optional and you don't have to take part, it won't affect your participation in the rest of the study.

The timeline below shows what will happen as you progress through the study:



If you are interested in learning more about the study, please continue to read the patient information leaflet which will provide you with more detail.

