Observational Cohort Trial -T-cells Antibodies and Vaccine Efficacy in SARS-CoV-2

Lay summary preliminary results

COVID-19 vaccines have been shown to work well in protecting against COVID-19 infection, although studies have mainly been in people **without** significant health problems. The OCTAVE trial is investigating whether people with health problems or treatments that affect their immune system are also protected by COVID-19 vaccines. The vaccines work by stimulating the body's immune system to produce antibodies that can protect against COVID-19 infection.

The OCTAVE trial has recruited patients with diseases or treatments that supress the immune system, including some types of cancers, rheumatoid arthritis, psoriatic arthritis, ANCA-Associated Vasculitis (AVV), inflammatory bowel disease, chronic liver disease, kidney disease, stem cell transplant and chimeric antigen receptor (CAR) T recipients. Participants received the Pfizer/BioNTech or Astra Zeneca vaccine as part of the National UK COVID-19 vaccination programme. Blood samples were taken around 4 weeks after the second vaccine dose to measure the antibodies that should be increased by the vaccine. These antibodies work against the coronavirus spike protein (a protein on the surface of the virus that helps it invade human cells) and are called "Anti-S antibodies".

The OCTAVE trial is not yet completed but has recruited 2,592 patients so far. We are still collecting data and testing the blood samples, so not all the information has been analysed yet. However, we do have some early and preliminary results on 600 patients that we want to share. We also compared our results with the results from another study (called PITCH) of people without health problems.

- More than 83% of participants in all groups had detectable anti-S antibodies 4 weeks after their second vaccine, with the exception of the AAV group receiving rituximab treatment where only a quarter showed an antibody response.
- Overall, almost 90% of the participants tested had detectable anti-S antibodies after their two vaccines. In comparison, 100% of the healthy people in the PITCH study had antibodies after their two vaccines.
- We also found that, depending on the type of disease or treatment, the levels of anti-S antibodies were lower in OCTAVE participants than the levels seen in the healthy PITCH participants.
- Interestingly, most participants had a similar response to healthy individuals in another part of their immune system (T cells) to the coronavirus spike protein.

No one knows yet what level of antibody is needed to protect against severe COVID-19 infection.

We are continuing to collect and analyse our data in more detail to confirm these findings and see if we can identify factors, including specific treatments that are linked with lower response to vaccines. Our results support the need to investigate further vaccination strategies to improve the immune responses against COVID-19 in patients whose immune systems are affected by illness or the treatments they receive.

We have already started a new trial called OCTAVE-DUO, which will test whether giving a top-up vaccination will stimulate a better antibody response in those people with a low antibody response after two doses.