8th June 2020

Dear Participant

A phase 2/3 study to determine the efficacy, safety and immunogenicity of the candidate Coronavirus Disease (COVID-19) vaccine ChAdOx1 nCoV-19

Thank you for taking part in the study. We would like to update you with some information relating to recent changes in the study. Please find enclosed an updated *Participant Information Sheet Version 4.0,* with the key changes underlined and summarised below.

The vaccine ChAdOx1 nCoV-19 was first given to 500 healthy adults in Oxford in April 2020 as part of a separate safety trial (COV001). Including in this current trial (COV002), the vaccine has now been given to approximately 2000 people in total with no unexpected safety concerns to date.

We are not sure what dose of vaccine is most likely to be protective against COVID disease. Vaccine doses are measured using standard scientific test methods. The vaccine received by the first approx. 1500 participants in the current COV002 trial was based on a dose measured using one type of scientific test. Participants in Group 6 will have a dose measured using a different type of scientific test which will give a similar dose of vaccine to that used in our earlier COV001 trial.

We are interested in evaluating both doses in the trial so that we can provide the data needed to inform policymakers on how to use the vaccine, if the vaccine is shown to work. This may help us understand which dose is the most effective. We monitor all trial participants very closely during the trial and we are collecting blood samples to measure the immune response.

We don't know which dose, if any, will provide protection. This does not mean that either dose will be better or worse and we will study the immune response carefully to identify any differences. We are also considering whether two doses of the vaccine might be needed and will further investigate this when we obtain the first results of the ongoing trials.

What does this mean for you?

Why wasn't the same dose used for all the groups in COV002 as in the first study, COV001?

There are several different ways of measuring the dose of the vaccine at the end of the manufacturing process. The dose was measured using a laboratory test that indicated it was similar to the first COV001 study. Alternative testing shows that the dose is lower than this measurement, but still in the normal range of doses that are used in clinical trials. We can now evaluate how well the vaccine works at the different doses as part of the study.

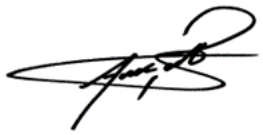
What if I have already been vaccinated, does that mean I won't be protected?

We don't know which dose will be protective and so it is not possible at the moment to determine which dose is needed for protection. The lower dose is likely to be better tolerated and, if it can provide protection, it might be better for use in vaccine programmes.

This change to the study design has been approved by the Medicines & Healthcare products Regulatory Agency (MHRA) and the Research Ethics Committee.

Thank you for your help and please do not hesitate to contact us if you require any further information.

Yours sincerely,



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