World-first COVID-19 alternating dose vaccine study launches in UK

- Clinical trial looking into alternating COVID-19 vaccine doses launched today in the UK
- Current programme of 2 doses of the same vaccine over 12 weeks remains unchanged
- Innovative study backed by £7 million of government funding

Patients taking part in a new clinical study launching today will soon receive different COVID-19 vaccines for their first or second dose.

Backed by £7 million of government funding, the study will be the first in the world to determine the effects of using different vaccines for the first and second dose – for example, using Oxford University/AstraZeneca's vaccine for the first dose, followed by Pfizer/BioNTech's vaccine for the second.

The study, run by the National Immunisation Schedule Evaluation Consortium (NISEC) across 8 National Institute for Health Research (NIHR) supported sites, will also gather immunological evidence on different intervals between the first and second dose for a mixed-vaccine regimen against control groups when the same vaccine is used for both doses.

A same-dose regimen is currently implemented for the national COVID-19 vaccination programme, and there are no current plans for this to change. Anyone who has received either the Pfizer or AstraZeneca vaccination as part of the UK-wide delivery plan will not be affected by this study. They will receive their second dose from the same source and over the same 12-week interval.

The 13-month study will monitor the impact of the different dosing regimens on patients' immune responses, which have the potential to be higher or lower than from the same dose regimen. Initial findings are expected to be released in the summer. The study has received ethics approval from the Research Ethics Committee, as well as approval from the Medicines and Healthcare products Regulatory Agency (MHRA).

Should the study show promising results, then the government may consider reviewing the vaccine regimen approach if needed, but only if proven to be safe and recommended by the Joint Committee on Vaccination and Immunisation (JCVI).

Minister for COVID-19 Vaccine Deployment, Nadhim Zahawi, said:

> This is a hugely important clinical trial that will provide us with more vital evidence on the safety of these vaccines when used in different ways.
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> Nothing will be approved for use more widely than the study, or as

> part of our vaccine deployment programme, until researchers and the regulator are absolutely confident the approach is safe and effective.
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> This is another great step forwards for British science, expertise and innovation, backed by government funding – and I look forward to seeing what it produces.

Deputy Chief Medical Officer and Senior Responsible Officer for the study, Professor Jonathan Van-Tam, said:

> Given the inevitable challenges of immunising large numbers of the population against COVID-19 and potential global supply constraints, there are definite advantages to having data that could support a more flexible immunisation programme, if needed and if approved by the medicines regulator.
>
> It is also even possible that by combining vaccines, the immune response could be enhanced giving even higher antibody levels that last longer; unless this is evaluated in a clinical trial we just won't know.
>
> This study will give us greater insight into how we can use vaccines to stay on top of this nasty disease.

The study will initially have 8 different arms testing 8 different combinations, but more products may be added. The 8 arms include:

- 2 doses of the Oxford/AstraZeneca vaccine at 28 days apart
- 2 doses of the Oxford/AstraZeneca vaccine at 12 weeks apart – as a control group
- 2 doses of the Pfizer/BioNTech vaccine at 28 days apart
- 2 doses of the Pfizer/BioNTech vaccine at 12 weeks apart – as a control group
- the Oxford/AstraZeneca vaccine for the first dose, followed by the Pfizer/BioNTech vaccine for the second, at 28 days apart
- the Oxford/AstraZeneca vaccine for the first dose, followed by the Pfizer/BioNTech vaccine for the second, at 12 weeks apart
- the Pfizer/BioNTech vaccine for the first dose, followed by the Oxford/AstraZeneca vaccine for the second, at 28 days apart
- the Pfizer/BioNTech vaccine for the first dose, followed by the Oxford/AstraZeneca vaccine for the second, at 12 weeks apart

Over 800 patients are expected to take part in the study, referred to as the COVID-19 Heterologous Prime Boost study or 'Com-Cov', across 8 different sites across England – including in London, Birmingham and Liverpool.

Patients will be recruited over the course of February via the NHS COVID-19 Vaccine Research Registry, with vaccinations expected to start towards the middle of the month and initial results to be made available over the summer

period. The UK public can volunteer to be contacted about taking part in the study and further vaccine studies by joining the registry.

The study has been classified as an Urgent Public Health study by the NIHR and is being undertaken by NISEC and the Oxford Vaccine Group, with funding of £7 million from the government through the Vaccines Taskforce.

Chief Investigator Matthew Snape, Associate Professor in Paediatrics and Vaccinology at the University of Oxford, said:

> This is a tremendously exciting study that will provide information vital to the roll out of vaccines in the UK and globally. We call on those aged 50 years and above who have not yet received a COVID-19 vaccine to visit our website to find out more about the study and see if there is a study site near them.
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> If we do show that these vaccines can be used interchangeably in the same schedule this will greatly increase the flexibility of vaccine delivery, and could provide clues as to how to increase the breadth of protection against new virus strains.

National Clinical Lead for the NIHR COVID Vaccine Research Programme, Professor Andrew Ustianowski, said:

> This is another exciting step forward in finding a variety of vaccine options for the UK and globally, for which the NIHR is integral to ensuring the participant recruitment for this study and the gaining of robust data on safety and effectiveness.
>
> We need people from all backgrounds to take part in this trial, so that we can ensure we have vaccine options suitable for all. Signing up to volunteer for vaccine studies is quick and easy via the NHS Vaccine Research Registry.

Interim Chair of the government's Vaccines Taskforce, Clive Dix, said:

> Thanks to funding from the Vaccines Taskforce, this study will give us valuable insight into how vaccines work together and could give us more flexibility as we continue to tackle this virus in the weeks, months and years ahead.
>
> This is yet another example of the UK leading the way in vital research into COVID-19 – and something that people both in this country, and around the world, could benefit from.

Volunteers for the study can sign up on the NHS website

This study is separate to the COVID-19 national immunisation programme.

Vaccines are not being mixed as part of rollout of the national COVID-19 immunisation programme.

The trial sites include:

- London – St George's and UCL
- Oxford
- Southampton
- Birmingham
- Bristol
- Nottingham
- Liverpool

The Vaccines Taskforce was set up under the Department for Business, Energy and Industrial Strategy (BEIS) in May 2020, to ensure that the UK population has access to clinically effective and safe vaccines as soon as possible, while working with partners to support international access to successful vaccines. This is to place the UK at the forefront of global vaccine research, development, manufacture and distribution.

The Vaccines Taskforce comprises a dedicated team of private sector industry professionals and officials from across government who are working at speed to build a portfolio of promising vaccine candidates that can end the global pandemic.

The Vaccines Taskforce's approach to securing access to vaccines is through:

- procuring the rights to a diverse range of promising vaccine candidates to spread risk and optimise chances for success
- providing funding for clinical studies, diagnostic monitoring and regulatory support to rapidly evaluate vaccines for safety and efficacy
- providing funding and support for manufacturing scale-up and fill and finish at risk so that the UK has vaccines produced at scale and ready for administration should any of these prove successful

Through the Vaccines Taskforce, the UK has secured early access to 407 million doses of 7 of the most promising vaccines so far. To date, the government has invested over £300 million into manufacturing a successful vaccine. In the Chancellor's Spending Review, published on 25 November, it was announced that the government has made more than £6 billion available to develop and procure successful vaccines.

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Oxford is world-famous for research excellence and home to some of the most talented people from across the globe. Our work helps the lives of millions, solving real-world problems through a huge network of partnerships and collaborations. The breadth and interdisciplinary nature of our research sparks imaginative and inventive insights and solutions.

Through its research commercialisation arm, Oxford University Innovation,

Oxford is the highest university patent filer in the UK and is ranked first in the UK for university spinouts, having created more than 200 new companies since 1988. Over a third of these companies have been created in the past 3 years.