

[New study into COVID-19 vaccine dose interval for pregnant women](#)

- New government-funded clinical trial investigating best COVID-19 vaccine dose interval for pregnant women launched in England
- Research shows pregnant women more likely to become seriously ill from COVID-19 and 98% of those in hospital due to COVID-19 are unvaccinated

The country's largest clinical trial investigating the best gap between first and second COVID-19 vaccine doses for pregnant women is being launched in England today (Tuesday 3 August).

Following 130,000 pregnant women being vaccinated in the US and no safety concerns being raised, the Pfizer/BioNTech and Moderna vaccines were recommended by the independent experts at the Joint Committee on Vaccination and Immunisation (JCVI) for pregnant women in the UK. Almost 52,000 pregnant women in England have now been vaccinated – similarly, with no safety concerns reported.

Data published last week by NHS England and the University of Oxford also shows no pregnant women who have had both doses of a vaccine have been admitted to hospital with COVID-19. Only three have been admitted after having their first dose, meaning 98% of those admitted to hospital have not received a jab.

The Preg-CoV study, backed by £7.5 million of government funding and led by St George's, University of London, will provide vital clinical trial data on the immune response to vaccination at different dose intervals – either four to six weeks or eight to 12 weeks.

This data will help determine the best dosage interval and tell us more about how the vaccine works to protect pregnant mothers and their babies against COVID-19.

Minister for COVID-19 Vaccine Deployment Nadhim Zahawi said:

Pregnant women are more likely to get seriously ill from COVID-19 and we know that vaccines are safe for them and make a huge difference – in fact no pregnant woman with two jabs has required hospitalisation with COVID-19.

This government-backed trial will provide more data about how we can best protect pregnant women and their babies, and we can use this evidence to inform future vaccination programmes.

I encourage anyone who is pregnant and eligible to sign-up and contribute to research that will save lives for years to come.

Vaccines have been given to pregnant women to protect them and their babies from diseases for years – including for whooping cough and flu.

The trial will involve over 600 pregnant women being vaccinated with either the Pfizer/BioNTech or the Moderna vaccine. They will be closely monitored by health professionals throughout their pregnancy and following the birth, with the safety of the women taking part in the trial the utmost priority.

The Preg-CoV participants will need to be between 18 and 44 years old, have no health conditions and be between 13 and 34 weeks pregnant on the day of vaccination. They will receive two doses of a COVID-19 vaccine – or one dose if they've already had their first – at either the shorter interval of four to six weeks, or the longer interval of eight to 12 weeks.

They will be scheduled to attend nine visits in total and will be required to complete an electronic diary between visits on any symptoms. They will also be given a 24-hour mobile number so they can contact one of the trial team at any time if they have concerns.

The scientists behind the trial will analyse blood samples from the participants and one blood sample from their newborn babies, alongside samples from breastmilk. They will use the samples to help understand more about how the vaccines are protecting these individuals from COVID-19, with initial results expected by the end of the year.

The study will open for applications from volunteers today via the study's website, with vaccinations set to start from mid-August. Participants will also be recruited to the study by invites sent through the NHS COVID-19 Vaccine Research Registry, which allows research teams to speak to suitable volunteers who have signed up to be contacted about taking part in vaccine studies.

Chief Investigator and Professor of Paediatric Infectious Diseases at St George's, University of London, Professor Paul Heath said:

Tens of thousands of pregnant women have now been vaccinated in both the US and the UK with no safety concerns reported, but we still lack robust, prospective clinical trial data on COVID-19 vaccines in pregnant women. This includes the best schedule to use to maximally protect them against COVID-19.

We are extremely pleased to commence the Preg-CoV trial, which aims to fill these gaps in our knowledge and will ultimately inform policy recommendations on the optimal use of COVID-19 vaccines in pregnancy.

The trial will be run across 13 National Institute for Health Research (NIHR) sites in England – including in London, Liverpool and Leeds. All the trial sites are working on ways of including participants from a wide variety of backgrounds and individuals from ethnic minorities are encouraged to apply.

The vaccination programme continues its phenomenal progress towards vaccinating the adult population of the UK, with over 85,336,436 vaccines administered in total – 46,872,411 first doses (88.6%) and 38,464,025 second doses (72.7%).

Further analysis from PHE and the University of Cambridge also suggests vaccines have so far prevented over 52,600 hospitalisations, an estimated 22 million infections and more than 60,000 deaths in England alone.

Dr Pat O'Brien, Vice President of the Royal College of Obstetricians and Gynaecologists, said:

We now have robust data of nearly 200,000 women from across the US and the UK, who have received the COVID-19 vaccine with no safety concerns. This tells us that both the Moderna and Pfizer vaccines are safe in pregnancy. However, more research is needed to monitor and understand how pregnant women respond to the COVID-19 vaccine.

We welcome this trial as the next step in further monitoring the protection provided by the vaccine, to understand the risk of any potential adverse side effects, and observe the immune response within those who are pregnant and their babies.

We encourage all pregnant women to get vaccinated, as the protection that it provides against COVID-19 to both mother and baby outweigh the risks. We are seeing more pregnant women being admitted to hospital with COVID-19, and we know that the Delta variant is causing more pregnant women to have severe illness than previous strains of the virus.

We hope that this research will help to gain the confidence of pregnant women that the recommendation of vaccination in pregnancy is based on robust evidence.

Professor Nick Lemoine, Medical Director, NIHR Clinical Research Network, said:

The fact that every participant in this study receives an approved vaccine will give volunteers peace of mind that they are protected from the virus and that they can take confidence in the safety of these vaccines, and the monitoring involved in the study.

Vaccine studies like this remain crucial for researchers to gain more information on the best intervals and methods to help protect

the whole population against COVID-19.

It is thanks to the continued dedication and commitment of volunteers that we are at this stage of research and the NIHR is very grateful for their efforts.

The NHS COVID-19 Vaccine Research Registry continues to help us reach out to potential participants and recruit to additional studies as we keep moving forward, and we encourage interested members of the public to sign up to be contacted at nhs.uk/ResearchContact.

Notes to Editor:

- Volunteers can sign up to the trial [here](#)
- The trial was commissioned by the Department of Health and Social Care through the National Institute for Health Research (NIHR) and funded by the Vaccine Taskforce, with the study being undertaken by St George's, as part of the National Immunisation Schedule Evaluation Consortium (NISEC).
- Participants will be blinded to the vaccine they receive. The majority of participants will also be blinded to the interval between doses. This will be done by incorporating the routine whooping cough vaccine into the trial schedule. Participants will be followed up for one year after their baby is born.
- NHS England research on pregnant women in hospital due to COVID-19 can be found [here](#)
- This trial has received ethics approval by the NHS Research Ethics Committee (part of the Health Research Authority), as well as approval from the Medicines and Healthcare products Regulatory Agency (MHRA).
- Latest PHE stats on vaccine effectiveness can be found [here](#)

Volunteering for COVID-19 vaccine clinical trials:

- People wishing to volunteer to support clinical trials can sign up for information on COVID-19 vaccine trials with the NHS COVID-19 Vaccine Research Registry, developed in partnership with NHS Digital. It is helping large numbers of people to be recruited into trials, meaning more effective vaccines for coronavirus can be found as soon as possible.

The hospitals taking part are:

- St George's University Hospitals NHS Foundation Trust
- University Hospital Southampton NHS Foundation Trust
- St Michael's Hospital, University Hospitals Bristol and Weston NHS Foundation Trust
- Liverpool Women's NHS Foundation Trust
- Leeds General Hospital, Leeds Teaching Hospitals NHS Trust
- St. Helier Hospital, Epsom and St Helier University Hospitals NHS Trust
- Hammersmith Hospital, Imperial College Healthcare NHS Trust
- Princess Royal Hospital, Shrewsbury and Telford Hospital NHS Trust
- Royal Free NHS Foundation Trust
- The Royal Cornwall Hospitals NHS Trust
- Royal Preston Hospital, Lancashire Teaching Hospitals NHS Foundation Trust
- Manchester University NHS Foundation Trust
- Birmingham Heartlands Hospital, University Hospitals Birmingham NHS Foundation Trust