**COVID-19 Vaccine Clinical Trial in Northern Ireland (Novavax)**

Hello,

Thank you for your interest in participating in this Covid-19 vaccine trial. We wanted to give you some more information on the trial.

***Please take some time to read through the Trial Information section below***

Once you have done that, and if you would like to find out more about the trial and can confirm that you agree with the following statements:

* I am between 18 and 84 years old
* I have not previously tested positive for Covid-19
* If female, I am not pregnant or breast feeding
* I understand that I need to attend a minimum of 6 study visits in Belfast over approximately a 13 month period

Then please email us your ***name*** and ***telephone number,*** and a preferred time for us to contact you (e.g. morning, afternoon ; although we cannot guarantee that we will be able to ring you at that time).

We will recruit people with, *and* without medical conditions, but so that we can put you in contact with the team that are best placed to deal with any queries you may have, please reply to the following emails

- if you have ***no*** medical conditions, please contact us at:

[No-conditions@belfasttrust.hscni.net](mailto:No-conditions@belfasttrust.hscni.net)

- if you have any medical conditions, please contact us at:

[Yes-conditions@belfasttrust.hscni.net](mailto:Yes-conditions@belfasttrust.hscni.net)

***We will reply to all of you in due course, but please bear with us as we expect to receive a large number of queries.***

Your information will only be accessible to staff working on the Covid-19 vaccine trials, it will not be shared with anyone outside the staff working on Covid-19 vaccine trials and, will be stored securely at all times. It will only be used to contact you to discuss participating in this trial or any further Covid-19 vaccine trials, and it will be destroyed when the Covid-19 vaccine trials are completed.

Thank you for taking the time to consider taking part – we really appreciate it.

We hope to hear from you soon!

Yours sincerely,

**The NI Vaccine Trial Team**

***Trial information***

**A new clinical trial to assess the efficacy and safety of a novel COVID-19 vaccine**

**The purpose of this clinical trial is to test a new vaccine against COVID-19 and we are looking for volunteers to take part.**

         if you are aged 18-84 and in good health, you could be eligible to participate

         the study involves a minimum of 6 visits over a period of around 13 months

**Background**

A new virus causing respiratory disease emerged in Wuhan, China in December 2019 and has since rapidly spread to many other countries around the world, despite containment efforts.

The virus is part of the Coronavirus family, which may cause respiratory infections ranging from the common cold to more severe diseases. This recently discovered coronavirus (called SARS-CoV-2) causes a disease called COVID-19.

There are no currently licensed vaccines for COVID-19. Vaccines are the most cost effective way of controlling outbreaks and the international community has stepped-up their efforts towards developing a vaccine against COVID-19.

**Aims of the study**

This new clinical trial will enable the study team to assess if people aged 18-84 years can be protected from COVID-19 with this investigational vaccine called (SARS-CoV 2 Recombinant(r) Spike (S) Protein Nanoparticle Vaccine (SARSCoV2 rS) with Matrix-M adjuvant).

It will also give valuable information on the safety aspects of the vaccine.

**Key dates**

The recruitment start and end dates in Northern Ireland are as follows:

Start:  2 October 2020

End:  30 January 2022

**What does taking part involve?**

During this study, we will recruit up to 9000 volunteers who will be randomly assigned to one of two groups.

One group will be vaccinated with the COVID-19 investigational vaccine and the other group will be vaccinated with a saline placebo. Saline is a mixture of salt and water. A placebo is a substance that has no therapeutic or medicinal effect and is used regularly in testing new drugs.  Volunteers will not know which group they are in.

Participants will receive 2 doses, around 21 days apart. In addition, they will have blood tests and nasal/throat swabs. The study team will collect information about any COVID-19 related symptoms that occur in participants during the trial.

Everyone taking part, no matter which group they are assigned to, will need to attend at least 6 visits to the local study site over a period of around 13 months.

**Please refer to the information sheet for full details of procedures and potential risks.**

**Who can take part?**

Participants who are likely to have had higher exposure to COVID-19 will be prioritised.  This is to help increase the likelihood of seeing an impact from the treatment.

In order to be considered to take part

you must:

* Be aged between 18 and 84 years (inclusive)
* Be in good health

you must **NOT:**

* Have tested positive for COVID-19
* Be pregnant, intending to become pregnant, or breastfeeding during the trial
* Have previously taken part in a trial with a coronavirus vaccine

**Where can I take part?**

The trial is being run in the Belfast City Hospital Site.

**Questions about taking part in vaccine studies**

Read a list of [frequently asked questions](https://bepartofresearch-uat.nihr.ac.uk/vaccine-studies/#Frequently%20asked%20questions%20about%20vaccine%20studies) from members of the public about taking part in vaccine studies.

**Questions about this study**

**What will happen if I don’t want to carry on with the study?**

Participation is voluntary and you are free to change your mind and withdraw at any time. You do not need to provide a reason.  This will not affect your subsequent medical care in any way. If you withdraw from taking part, we might need to offer you a follow up visit, for example to check the vaccination site or a blood result.

**What are the advantages of taking part?**

Knowledge gained from this study will help us develop a vaccine against the newly emerged coronavirus disease COVID-19. Participation could really make a difference during a public health emergency.

**Are there any risks from taking part?**

Although this is a new vaccine, similar investigational vaccines have been widely administered for other conditions without significant safety concerns. The risks and side effects of the proposed study procedures are:

* Blood samples: drawing blood may cause slight pain and occasionally bruising
* Vaccinations:  Common side effects are some mild redness and swelling at the injection site. You may feel like you have flu-like symptoms within 24 hours of the vaccinations. These usually resolve within 48 hours.