NIHR | Southampton Clinical Research Facility

University of Southampton

NHS University Hospital Southampton NHS Foundation Trust

PARTICIPANT INFORMATION SHEET: COV001

A study to assess a new COVID-19 vaccine in healthy adults

We would like to invite you to take part in our COVID-19 vaccine study. Before you make a decision, it is important you take the time to understand why we are doing this research and what it would involve. Please read the following information carefully and consider discussing it with friends and relatives.

The trial will involve up to 1112 volunteers. We will randomly sort 1102 volunteers so that half will be given the COVID-19 vaccine and half will receive a control. You won't know whether you received the COVID-19 vaccine or not until the trial is completed.

What is the purpose of this research study?

The purpose of this study is to test a new vaccine against COVID-19 in healthy volunteers.

This study will enable us to assess if healthy people can be protected from COVID-19 with this new vaccine. It will also give us valuable information on safety aspects of the vaccine and its ability to generate good immune responses against the virus. We will do this by randomly allocating participants to receive the vaccine or a control injection in addition to doing blood tests and collecting information about any symptoms that occur after vaccination.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form. You are free to withdraw at any time and without giving a reason.

What are the advantages of taking part?

You will not necessarily gain any direct benefit from the trial, but the information gained from the study might help to develop an effective vaccine against COVID-19. If in the future you become exposed to COVID-19, you should not assume that the vaccine you received in this study will give you any protection against COVID-19.

What will happen if I decide to take part?

- Screening Visit – 2 hours (Review participant information sheet with an investigator, consent form, ID check, discuss medical history, physical examination, vital signs measured, blood test and urine sample)
- Vaccination Visits - 2.5 hours (vital signs, blood test, urine pregnancy test, receive vaccine, 1 hour observation in clinic after the vaccine)
- Electronic Symptom Diary "e-diary" – Completed at home. We will give you a thermometer, tape measure and an E-diary account to record all your symptoms and your temperature every day for 7 days after vaccination.
- Follow up visits – 30 minutes (check vital signs, blood tests, and check for side effects or new health problems)

Will I be paid for taking part in this trial?

You will be compensated for your time, the inconvenience of having blood tests and procedures, and your travel expenses. The total amount compensated will be approximately £25-235 depending on the exact number of visits and whether any repeat or additional visits are necessary.

Can I take part?

In order to be involved in the study you must:

a. Be a healthy adult aged between 18 and 55 years.
b. Be able and willing to comply with all study requirements. You must be able to attend study visits and not rely on public transport or taxis
c. Allow the Investigators to discuss your medical history with your GP.
d. Practice continuous effective contraception for the duration of the study (women of childbearing potential only).
e. Refrain from blood donation during the course of the study.

You cannot participate in this study if:

a. You have participated in another research study involving vaccines, medications or frequent blood samples or received any vaccines in the last 30 days .
b. You have had a blood transfusion in the 3 months preceding your involvement in this trial.
c. You have problems with your immune system or a history of cancer.
d. You are pregnant, breast feeding or intend to become pregnant during the study.
e. You have a history of a severe allergic reaction .
f. You have a history of a serious psychiatric condition that may affect participation in the study.
g. You have any other serious long-term illnesses requiring hospital follow-up,
h. You have a chronic respiratory condition, including asthma
i. You have any of high blood pressure, diabetes, chronic kidney, liver, heart or neurological disease
j. You are seriously overweight (BMI ≥40 Kg/m2) or underweight (BMI ≤18 Kg/m2)
k. You drink on average more than 42 units of alcohol a week
l. You have injected recreational drugs at any time in the last 5 years
m. You were diagnosed with confirmed COVID-19 at any point
n. You have a new onset of a fever and a cough or shortness of breath or new onset of loss
o. of sense of smell or taste since February 2020
p. You live in the same household as any vulnerable groups at risk of severe COVID-19 disease
q. You are likely to have been previously exposed to COVID-19 (e.g. frontline healthcare worker seeing COVID-19 patients, had to self-isolate for any reason, had contact with a confirmed COVID-19 case)

Are there any risks from taking part in the trial?

The risks and side effects of the proposed vaccinations and trial procedures are**:**

- Blood samples - Drawing blood may cause slight pain and occasionally bruising at the site where the needle enters.
- Vaccination Side Effects - With any new medicine or vaccine there is always a possibility of an unexpected side effect. You will be provided with a 24h study mobile number. If you experience unexpected events or become in any way concerned you can use this to contact one of the study doctors at any time. We will ask you to record these symptoms in the E-Diary too.

Would my taking part in this trial be kept confidential?

- All information that is collected about you during the course of the research will be coded with a study number and kept confidential.

Further information and contact details:

If you would like further information about participating in research please visit the following website: http://www.nhs.uk/conditions/Clinical-trials/Pages/Introduction.aspx. For independent advice about participating in this trial you may wish to contact your GP.