



## Rechallenge *Staphylococcus aureus* Experimental nasal colonisation sTudy

### Study Summary

We are inviting people **aged 18 – 55 years**, who are **in good health** to help us **learn more about one of the leading causes of healthcare infections**.

***Staphylococcus aureus*** are bacteria that are carried harmlessly in the nose or on the skin of around 3 in 10 people. It can lead to mild infections on the skin or to more serious infections, such as joint, pneumonia, or in the blood (sepsis).

Researchers have been trying to develop a vaccine against these bacteria for decades, but despite many attempts, no human vaccine has been found that works. We want to understand more about the bacteria and how our bodies respond when we are carrying it, so that we can develop better treatments or vaccines to prevent serious illness. To do this some samples may be sent to other academic or commercial research partners to support some sample analysis who may use the research data to develop analytical tools, including Artificial Intelligence (advanced computer tools), to investigate immune responses.

In this research study we will use information from you/your medical records/your GP and/or hospital records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data in case we need to check it and for future research. We will make sure no-one can work out who you are from the reports we write. The information pack tells you more about this.



Oxford Vaccine Group,  
Oxford

01865 611400

info@ovg.ox.ac.uk

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A challenge study is where volunteers, who are in good health, are given **small amounts of the bacteria** and closely monitored, by taking samples, and making sure they are safe. By doing challenge studies, we can learn how the body responds and prevents infections.

Because the bacteria we will be giving are alive, there is a **small risk** that you may develop an infection or you may pass it to others who are vulnerable. For this reason, we would only enrol people to this study that **do not have a serious medical condition and do not live with or care for someone who has a weakened immune system, is over 65 years old, or is under 5 years old**. This includes health care providers having direct contact with patients. A more detailed list is in the full study information.

Because Staphylococcus aureus or Staph, has many different types or strains, we will first work out which strain will work best in a challenge and how many bacteria we need to give. To do this will need to enrol up to **192 people into Stage one**.

The **next stage**, will be to understand what happens when people are given the bacteria once and then are given the same bacteria again. We may also see what happens if people are given one strain first and then are given a different strain. These are both called a re-challenge. **Up to 192 people** will be enrolled in this stage.

Depending on the stage of the study, this is **what would be involved**:

- **Between 10 and 20 visits** to a clinic in the Oxford Vaccine Group over 56 days (2 months) 4 or 126 days (4 months). Visits take between 30 – 90 mins and will be on Mon – Fri. There will also be some 5 mins phone calls at months 2 and 6 or 8 depending the Stage you are in.
- We would **drip a small amount of the bacteria into your nose**, up to two times
- Before you are given the bacteria, you will be given a 5-day course of a **special wash to disinfect your hair and the rest of your body, as well as an antibiotic cream or ointment for your nostrils**. You will also be given this again at the end of the study
- We collect **blood samples and swabs from your nose, throat and skin**
- You will have 24hr contact with a study doctor
- We ask you to **complete short electronic diaries**, to make sure you are safe
- We will give you the equipment you need to take a very small **swab from inside your nose at home every day for 16 days** after you have been given the bacteria
- You will be reimbursed between £110 and £1300. Full details about the timing of reimbursements are included in the full study information

Although we do not expect you to have any severe symptoms, some **mild symptoms** such as those below may be experienced. If you needed to, you could take paracetamol.

- headaches
- sneezing
- a sore throat
- blocked or runny nose
- fever and chills
- general discomfort
- headache
- tiredness (fatigue)
- itchy or painful nose
- redness around the nostrils

We will closely monitor everyone who takes part and we will treat any infections that need antibiotics.

If you are interested in this study, there is more information available by following this link <https://www.ovg.ox.ac.uk/studies/reset>. When you have seen the full information about the study, you can register your interest using the link below.

If you have questions and would like to talk to a member of the study team, you can contact us at [info@ovg.ox.ac.uk](mailto:info@ovg.ox.ac.uk).

**If you are interested in taking part in this study, then please complete the online screening questionnaire at:**

<https://www.ovg.ox.ac.uk/studies/reset>



If you decide not to take part it would be really helpful to understand why. You will not have to give us any personal information. We hope that we can use the feedback to improve or change things about our studies in the future.

<https://www.ovg.ox.ac.uk/studies>

