

# Frequently Asked Questions

## What is AVIRS about?

Studies have shown an association between the amount and type of bacteria in the intestines (the gut microbiota) and the effectiveness of some vaccines, indicating that people with healthy gut bacteria may have better immune responses to vaccines than people with altered (poor) gut bacteria. When the bacteria in the gut are reduced, the immune response to vaccination may be muted, resulting in less protection against diseases.

We would like to find out if depletion of the gut bacteria (by using antibiotics) impairs the protection given by the BCG vaccine. We will assess this by comparing people that have taken a short course of antibiotics to people that have not taken antibiotics prior to BCG vaccination.

## What is the BCG vaccine?

The BCG vaccine protects against tuberculosis (TB) and is one of the most widely-used vaccines in the world. It is routinely given to certain groups of Australians with a higher risk of tuberculosis, and routinely given during infancy in other countries. The BCG vaccine is given into the skin of the arm (intradermally) and causes a small sore (papule) which heals into a small flat scar.

## What is the Yellow Fever vaccine?

The Yellow Fever vaccine is used to prevent infection with yellow fever virus – a mosquito-borne virus present in some tropical areas. The Yellow Fever vaccine is given routinely in Australia as a travel vaccination to people travelling to areas of Africa and South America. The Yellow Fever vaccine is given subcutaneously (under the skin) or intramuscularly (into the muscle).

## What's involved in this study?

This study involves taking a short course of antibiotic tablets (or no antibiotic tablets) prior to vaccination with the BCG or placebo (saline). We will collect several blood samples and ask you to provide stool samples (self-collected at home) around this time.

There will be a period of 3-6 months with no study visits. Then, you will receive either a yellow fever vaccination at 3 months or a second BCG vaccination at 6 months. If you receive the BCG vaccine at 6 months, we will also collect a small skin sample (biopsy) of the vaccination site.

## How often are study visits?

There will be three study visits in month one of the study (visits every 1-2 weeks).

If you are in the Yellow Fever Vaccination arm of the study, you will not have any more visits until month 4 of the study. You will have one visit for the Yellow Fever Vaccination, and additional visits for blood tests at 2, 5 and 7 days post vaccination.

If you are in the BCG-revaccination arm of the study, you will not have any more visits until month 7 of the study. You will have one visit for the BCG re-vaccination, and another visit 2 weeks later to collect a skin sample (biopsy) of the re-vaccination site.

## What are the benefits of taking part?

Results from this study may help us to design better vaccines or make vaccines work better, which may help people in the future.

We cannot guarantee that you will receive any benefits from this trial. Depending on your randomisation group, you will receive the BCG and/or yellow fever vaccine which provide may protect you from getting sick with tuberculosis (a lung infection that is uncommon in Australia) or yellow fever (a viral infection that is uncommon in Australia).



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## What are the risks of taking part?

This study involves taking a course of antibiotics and receiving up to two vaccinations.

There are no experimental vaccines or treatments in this study – the BCG and yellow fever vaccines are both widely used and approved vaccines with known safety profiles. As with all vaccines, you may experience some side effects following vaccination (eg. Soreness or swelling at the vaccination site).

There are no major risks of taking antibiotics, however they may cause some gastrointestinal symptoms which usually clear up in a couple of days.

Vaccination and blood tests will be conducted by trained, experienced medical staff. A dedicated medical team member will also be available to discuss any side effects you may experience while taking part in the study.

## Will I know which vaccine group (BCG or placebo) I am in?

As this study is blinded, you will not know which vaccine group you are in during the study. However, at the end of the study we will tell you whether you received the BCG vaccine or placebo.

## Why do you need blood and stool samples?

We will collect multiple blood sample through the study. These will be used to test for baseline immune function and also immune responses following vaccination.

Stool samples will be used to assess the level and type of microbes in the gut before and after antibiotics, and at the end of the study.

## Do I receive compensation for taking part of in AVIRS?

Yes, participants will receive \$500-\$750 for participating in the study, depending on the study arm you are enrolled to. This will be pro-rated (payment spread throughout the study period).

