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# BIO-005: ABBREVIATED PARTICIPANT INFORMATION SHEET

A study to test malaria vaccine efficacy using a malaria challenge.

## Why are we conducting this study?

Malaria is a disease caused by an infection transmitted by mosquitoes. It causes **over 600,000 deaths** every year, mainly in countries in Africa. Most of these are **children** under the age of 5 years who can experience breathing difficulties, kidney failure and seizures due to severe forms of the disease.

Figure 1. This picture shows a young child with severe malaria[1]

There are now two approved malaria vaccines; however, while these vaccines will save many lives, they are only partially effective.

**The BIO-005 study is trying to understand how a new vaccine can protect people from severe malaria.**

Help us in the fight against malaria!

**Did you know? A child dies of severe malaria almost every minute.**

## Who can take part?

Are you:

- ✓ A healthy adult aged 18-45 years;
- ✓ Who has never had malaria before;
- ✓ Is not pregnant, breastfeeding or planning on falling pregnant; and
- ✓ Able to attend study visits in Oxford over an approximate 6-month period?

## You may be able to take part!

Please see the Participant Information Sheet for a complete list of eligibility criteria.

**Did you know? After clean water, vaccination is the most effective public health intervention in the world for saving lives and promoting good health.**

## What does the study involve?

**We are testing a new vaccine which interferes with the malaria parasite getting into blood cells. (See more below!)**

We would like to test our vaccine by performing a **malaria challenge**.
A malaria challenge is where we infect you with malaria under carefully controlled conditions.
We then **monitor** your infection levels using blood tests and **start treatment with effective malaria tablets** when your infection levels have risen but are still low enough to **completely clear the infection**.

More than **600 people** have previously had a malaria challenge as part of a clinical trial in Oxford! Watch this video hear about their experiences!

## Which malaria vaccine(s) are being tested in this study and where do they come from?

The vaccines we are testing in this study are called **"R78C"** and **"RH5.1".**
They are given with an "adjuvant" (helper substance) called **"Matrix-M".**
RH5.1 and R78C are both **protein vaccines:** they contain small protein pieces from the parasite that causes malaria.
These proteins have been chosen because they **trigger a strong immune response**.
Protein vaccines have been **used safely for decades.**

**RH5.1** is based on part of a malaria protein known as **RH5**.
**R78C** is based on parts of malaria proteins known as **RIPR and CyRPA**.
The malaria parasite uses these proteins as a **"key"** to get into red blood cells (see **Figure 1** below).
This is the main reason why people get sick from malaria.

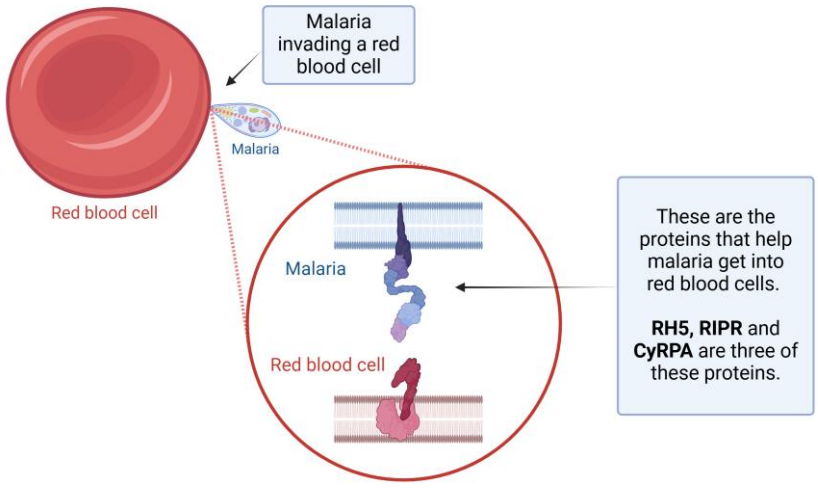
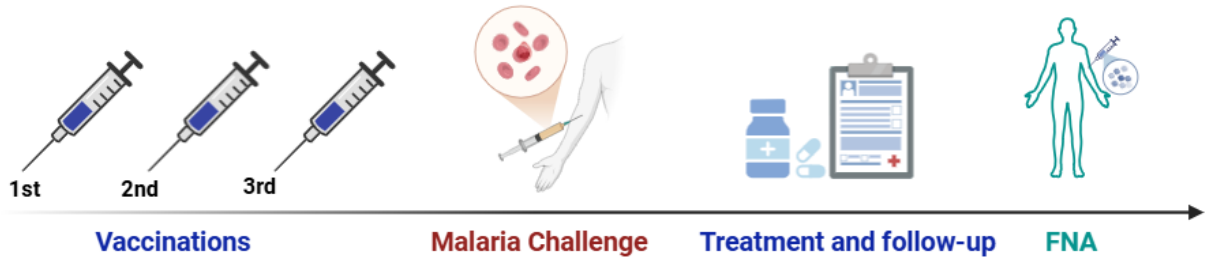



Figure 1: Illustration showing invasion of the red blood cells by malaria[2]

## What does the schedule look like?

We will recruit **two groups of participants**.

Group 1 (~9 months)




Group 2 (~3 months)


## What are the study procedures?

1. Vaccinations

Vaccinations will be given into the muscle of the **upper arm**.
We will ask participants **to wait for 60 minutes** after each vaccination to check there are no immediate problems. You may have some pain, redness, swelling, and/or flu-like symptoms.
The majority of symptoms are likely to be mild.

2. Malaria Challenge

A small volume of fluid that contains the malaria infection will be given through a drip ("cannula") in your arm. After the malaria challenge, you can go home and continue with your usual activities. However, we will need to check you every day so that we can start antimalarial tablets once you have a detectable infection. **We ask that you remain in the Oxford area** during this time so that we can start treatment promptly. **The study doctor is available 24/7.**

3. Fine needle aspiration (optional)

Fine needle aspiration (FNA) involves taking cells and fluid from a lymph node (gland).
Using an ultrasound scan for guidance, a needle will be used to collect a small amount of fluid and cells from the gland. You should not feel any pain but may feel some pressure. The FNA procedure itself takes only a few minutes but the visit may last approximately 1-2 hours. For more information, please read our Information Sheet on FNA procedures.

4. Blood samples will be taken at most study visits:

We will check routine blood counts; kidney and liver function; measure malaria infection levels and assess your immune response.

## Is there anything else I should know?

- Are there any risks or benefits of participating?

The vaccines in this trial have been shown to be safe in previous studies!
However, you may experience **fever, pain and/or swelling at the site of vaccination**.
The malaria challenge can be associated with **flu-like symptoms**. Untreated malaria infection can result in serious illness. Therefore, it is important that you attend all the clinic visits and take the anti-malarial treatment as advised. More information can be found in the Participant Information Sheet.

**Participating in this study will not benefit you directly**. However, it will greatly improve our development of more effective vaccines to stop children dying because of malaria.

- How do I sign up?

Thank you for your interest!
Please complete our online questionnaire by: **visiting our website or scanning this QR code**
The **questionnaire** takes 5 minutes and will ask questions to see if you could be eligible for participation. It will also ask for your contact details and arrange an in-person appointment.

- What happens next?

The next step is a screening appointment with one of the study doctors. This appointment lasts 1-2 hours and involves a detailed discussion about the trial, review of the full eligibility criteria, blood tests and a medical examination.

- How long and how frequent are the other visits?

The malaria challenge will require you to be present for most of the morning on the day of challenge. The FNA procedure (optional) will only take a few minutes, but the visit can be 1-2 hours. However, the other study visits are much quicker and generally take no more than 30 minutes. For your safety and monitoring, you will be required to visit the clinic daily and at times twice daily after the malaria challenge.

- How do I find out more information?

➢ More detailed information about this study can be found in the Participant Information Sheet. **We require you to read this document before you can be part of this study.**

➢ Find out more about **participating in this study** and other **malaria challenge studies** from our video about the **BIO-005 study** and malaria challenge video

➢ Contact us using the details below. **We would be more than happy to answer any queries!**

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## References

1. Image from Medicines for Malaria Venture, Africa-Europe partnership launches study to evaluate emergency response tools for severe malaria in highly isolated rural settings. Available at https://www.mmv.org/newsroom/news-resources-search/SEMAReACT-PR. Accessed 24th October 2024.
2. Created in BioRender. Bardelli, M. (2024) BioRender.com