Subject information for participation in medical research

Long term protection against malaria after a single GA2 immunisation (GACHA)

Official title: Late immunity after single immunization with genetically attenuated Plasmodium falciparum Δmei2 (GA2) sporozoites – a follow-up, controlled human malaria infection study

Introduction

Dear Sir/Madam,

With this letter, we would like to ask you to take part in a medical study. Participation is voluntary.
You can read about the medical study in this information sheet, what it means for you, and what the pros and cons are. It is a lot of information. Can you please read the information and decide if you want to take part? If you want to take part, you can fill in the form in appendix E.

Ask your questions

You can take your decision based on the information in this information sheet. We also suggest that you do this:
- Put your questions to the investigator who gave you this information.
- Talk to your partner, family or friends about this study.
- Ask questions to the independent expert, dr. A.H.E. Roukens. For contact details, go to appendix A.
- Read the information on www.rijksoverheid.nl/mensenonderzoek.

1. General information

The Leiden University Medical Center (LUMC) has set up this study. Below, we always call LUMC the 'sponsor'. Investigators, these can be doctors, nurses, doctor's assistants, or student assistants, conduct the study in the LUMC. Participants in medical-scientific studies are often called study participants. Both patients and healthy people can be study participants. This study needs a maximum of 20 healthy participants who are between 18 and 35 years old. Additionally, up to three reserve participants will be recruited, who can step in at the beginning of the study if one of the main participants is no longer able to take part. The Central Committee for Research with Human Subjects (In Dutch: Centrale Commissie Mensgebonden Onderzoek (CCMO)) approved this study.

2. What is the purpose of the study?

In this study we look at how long people who are immunized with genetically-attenuated GA2 malaria parasites remain protected against malaria. We study this in research participants

who, four years ago, received a single administration of GA2 malaria parasites through 50 mosquito bites. We aim to determine whether these participants are still protected against a malaria infection more than four years after the immunization. We compare this with a control group consisting of people who have not previously been exposed to malaria or a malaria vaccine.

3. What is the background of the study?

Approximately half a million people die from malaria every year, especially young children in Africa. The malaria parasite is transmitted by bites from malaria mosquitoes. The development of an effective vaccine against malaria is necessary to protect these children against malaria. There are currently two vaccines available against malaria, but these do not work optimally and require repeated vaccinations within one year.
The GA2 is a malaria parasite that has been weakened by genetic modification. This modification prevents the parasite from causing malaria. However, the GA2 malaria parasite can train people's immune systems to recognise and clear malaria parasites.
Previous research (CoGA study) showed that 50 mosquito bites with the GA2 malaria parasite provided good protection against malaria-infection, with nine out of the ten research participants being protected against malaria. A follow-up study (the CoGA rechallenge study), which investigated the duration of protection against malaria, showed that 4 out of 6 participants who had previously been protected against malaria were still protected two years after immunization. In the present study, we aim to investigate whether participants who, four years ago, received a single exposure to 50 mosquito bites carrying GA2 malaria parasites (in the GA2 study) are still protected against malaria. We will do this by exposing these participants to a malaria infection. This will allow us to assess how long protection against malaria lasts.

4. What happens during the study?

How long will the study take?
Are you taking part in the study? The study will take about five weeks in total. During the study you will visit the LUMC for a total of 23 times. Also, you will be receive two phone calls. After that, there will be two follow-up visits at 8 and 21 weeks after the end of the trial.

Step 1: are you eligible to take part?
The screening visit takes about one and a half hours. First, we want to know if you are eligible to take part. That is the reason that the investigator is doing some checks:

- Discussing your medical history and a history of cardiovascular disease in your close family members.
- Physical examination. For example, the investigator can listen to your heart and lungs and measure your blood pressure and heart rate.
- Blood test. The investigator will take some blood from you. We test your blood for HIV, hepatitis A, and hepatitis B. We will tell you if you have any of these diseases.
- Electrocardiogram (ECG).

- Urine test for the use of drugs such as cocaine and amphetamines.
- Pregnancy test for persons of childbearing potential (conducted on day before the mosquito exposure).

Please note: it is possible that you are not eligible for this study, even if you are healthy. The investigator will tell you more about this.

For this study, we will have 2 groups:

- Group 1. The people in this group have previously participated in the GA2 study (stage A, cohort 2). They have been immunised once with GA2 by 50 mosquito bites.
- Group 2. The people in this group have never been exposed to malaria. They are the control group.

Back-up study participants for group 2 stay in the trial until the exposure to malaria. A back-up participant attends the screening visit and study day 1 and attends study day 2 (exposure to malaria) as a back-up. If one of the participants drops out before the exposure, a back-up study participant can replace this participant.

Step 2: exposure to malaria
You will be infected with malaria to see if you are protected (= immune). The malaria infection will be done by exposing you to 5 infected mosquitoes on the forearms. This will be done in the LUMC and will take a full working day. After the exposure, you will visit the LUMC on a **daily basis for two weeks** for malaria blood tests. These control visits will take 15 minutes and will be held **between 7:00 and 8:30 in the morning**. Once we see that you have malaria you will be treated with the anti-malarial drug Malarone. We expect all participants in group 2 to develop malaria within 28 days. We do not know this for the participants in group 1. If you did not develop malaria 28 days after the exposure, you will receive the Malarone treatment as a safety measure. If a study subject does not tolerate the use of Malarone, or if the treatment with Malarone is not effective, the anti-malarial drug Riamet will be used as a treatment.

Step 3: study procedures and measurements
Blood tests
At every study visit to the LUMC, blood tests will be done. The investigator will do this by collecting 1 to 10 vials of blood each time. In total, we will not collect more than 500 mL of blood over a 12 week period. This amount does not cause problems in adults. For comparison: if you give blood at the blood bank, you give 500 mL at a time. With the blood test, we test these things:

- Do you have malaria?
- How does your immune system responds to the malaria parasites?

Appendix C has a list of the exact measurements we carry out during each visit.

5. What agreements do we make with you?

We want the study to go well. That is why we will make the following agreements with you:

- You visit every appointment.
- For 28 days after exposure to the mosquito bites, you should not perform intensive physical exercise (beyond your normal level). This means that you should not engage in sports activities that differ from what you are accustomed to. For example, if you usually go to the gym three times per week, you may continue to do so with the same frequency and intensity. If you normally do not exercise at all, we ask that you also do not start exercising during the first 28 days after exposure.
- You will not travel abroad for 28 days after being exposed to the mosquito bites, and will not go to malaria-endemic regions during the study.
- You will not take part in other medical research during this study.
- You carry a participant card of the study with you. In your wallet, for example. It states that you are taking part in this study. And who should be warned in case of an emergency. Show this card when you visit another doctor.
- From the exposure to malaria mosquitoes until 28 days after you can use a maximum of 3000mg (6 tablets of 500mg) of paracetamol per day.
- For 28 days after exposure to the mosquito bites, you should not consume excessive alcohol. This means that during this period you should not drink more than two alcoholic drinks per day.
- You should contact the investigator in the following situations:
    - You want to start taking other medication. Also if these are homeopathic remedies, natural remedies, vitamins or over-the-counter medicines.
    - You are hospitalised or get treatment in a hospital.
    - You suddenly have problems with your health.
    - You no longer want to take part in the study.
    - Your telephone number, address or email address changes.

Is it OK for you to get pregnant during the study?

Persons who are pregnant or breastfeeding cannot take part in this study. Participants should also not get pregnant during the study. Malaria can have consequences for an unborn child, for instance, causing growth retardation. Participantws of childbearing potential therefore need to use highly effective contraception during the entire trial. The investigator will tell you how best to prevent pregnancy. You can also review this information in appendix D. Talk to your partner about this.

Pregnant after all?

If you do become pregnant during the study, inform the investigator immediately. In this case, you should stop participating in the study as soon as possible in consultation with the investigator.

Are you allowed to donate blood during the study?

You are not allowed to donate blood or plasma during the study. You are not allowed to donate blood for at least 3 years following the end of the study. You will no longer be able to donate whole blood if antibodies against malaria remain detectable in your blood. However, you can still (continue to) donate plasma after this study has ended.

Check-up visits
Because it may be dangerous for your health to not get treated if there are malaria parasites detectable in your blood, it is very important that you are (on time) on every check-up visit after the exposure to malaria mosquitoes. If you are not there at the set time, we will call you several times until we have reached you. If you remain unreachable by phone, we visit you at home. We also ask for contact details of someone close to you, that we can contact if we cannot reach you.

6. What side effects, adverse effects or discomforts could you experience?

Infection with malaria
Infection with malaria parasites may result in malaria. This risk will differ from group to group. We expect that all participants in group 2 will get malaria. For group 1 the risk is unknown, but expected to be lower. Most people who develop malaria, experience some symptoms, lasting two to three days on average.
The main symptoms of malaria are:

- Headache;
- Fever;
- Shivering;
- General weakness and fatigue;
- Muscle and joint pain;
- Nausea;
- Dizziness.

The following side effects are rare but can be serious:

- Increase in liver enzymes;
- Inflammation of the heart muscle.

Immediately contact the investigator if you:

- Have pain in your chest;
- Become ill and get fever with or without shivering.

The anti-malarial drug Malarone
The anti-malarial drug Malarone may cause side effects. The following side effects are very common (more than 1 in 10 people): stomach ache, nausea, throwing up, diarrhoea and headache. Common (1 in 10 – 100) side effects are: decreased appetite, dizziness, difficulty sleeping, gloominess, vivid dreams, itch or rash. Occasionally (1 in 100 – 1.000 people),

palpitations, anxiety, hair loss or hives occurs. Rarely (1 in 1.000 – 10.000), hallucinations occur.

The antimalarial drug Riamet

If the exceptional situation occurs that you do not tolerate the use of Malarone, or when it is not effective to treat the malaria, the drug Riamet will be used as treatment. Common side effects are: headache, dizziness, palpitations, nausea, throwing up, tummy ache, diarrhoea, fatigue, muscle- or joint ache. In rare cases, further treatment is needed after Riamet when the parasite has not been treated effectively.

Inconvenience during blood sampling

Blood sampling can lead to inconvenience such as:
- Pain;
- Bruising.

Risk of malaria transmission to people in your surroundings

The chance that someone else will contract malaria as a result of your participation in this study is very small. All participants who test positive for malaria during this study will be treated at a very early stage, before they become infectious to others. As a result, the disease cannot be transmitted through mosquitoes. In addition, there are generally very few mosquitoes in the Netherlands that are capable of transmitting malaria. This further reduces the chance of transmission to others.

7. What are the pros and cons if you take part in the study?

Taking part in the study can have pros and cons. We will list them below. Think about this carefully and talk to other people about it.
You do not benefit from taking part in this study yourself. But if you take part you will help the investigators to get more insight into the prevention of malaria.

Taking part in the study can have these cons:

- You may experience side effects or adverse effects of the infection with malaria parasites, as described in Section 6.
- You may experience side effects or adverse effects from the anti-malarial treatment Malarone or Riamet, as described in Section 6.
- There may be some discomfort from the measurements during the study. For example: taking a blood sample can be a little painful. Or you could get a bruise as a result.
- Taking part in the study will cost you extra time.
- You have to comply with the study agreements.
- It is possible that something may be discovered during the study by chance that is not directly relevant to the research but may be important for your health. See also section 10 on incidental findings.

You do not wish to participate in the study?
It is up to you to decide if you wish to participate in the study

8. When does the study end?

The investigator will let you know if there is any new information about the study that is important to you. The investigator will then ask you if you want to continue to take part.

In these situations, the study will stop for you:

- All checks according to the schedule are finished.
- You have become pregnant.
- You want to stop participating in the study yourself. You can stop at any time. Report this to the investigator immediately. You do not have to explain why you want to stop. If you want to stop after you having been exposed to malaria parasites, you still have to take the anti-malarial drug Malarone and visit the hospital a few times for your own safety
- The investigator thinks it is better for you to stop. In this case, you still have to take the anti-malarial drug Malarone and visit the hospital a few times for your own safety.
- One of the following authorities decides that the study should stop:
    - the LUMC
    - the government, or
    - the Medical Ethics Review Committee assessing the study

What happens if you stop participating in the study?
The investigators use the data and body material that have been collected up to the moment that you decide to stop participating in the study. If you want, your material can be destroyed. Communicate this to the investigator.

The entire study ends when all the participants have finished.

9. What happens after the study has ended?

Will you get the results of the study?
About 6 months after the study has ended, the investigator will inform you about the most important results of the study.

10. What will be done with your data and body material?

Are you taking part in the study? Then you also give your consent to collect, use and store your data and body material.

What data do we store?
We store these data:
- your name
- your gender

- your address
- your date of birth
- your bank details (for payment at the end of the trial)
- information about your health
- (medical) information that we collect during the study
- We furthermore ask for your permission to take a photograph, which is kept in your file. These are used to verify your identity before any study procedures are performed. This photograph is destroyed after your last visit.

What body material do we store?
We will store bloods in vials.

Why do we collect, use and store your data and body material?
We collect, use and store your data and your body material to answer the questions of this study. And to be able to publish the results.
To answer the research questions of this study, body material will also be shared with Stanford University in the United States. This material is coded and therefore cannot be directly traced back to you. The researchers there will analyze this biological material to better understand how the immune system generates protection against malaria.

Before the material is sent, an additional test will be performed at the LUMC: an HLA typing (also called tissue typing). This test examines certain inherited characteristics of your immune system that determine how your body recognizes pathogens. This test will be performed on coded biological material and is only intended to answer the specific research question of this study. Therefore, the results of the HLA typing will not be shared with you.

How do we protect your privacy?
To protect your privacy, we give a code to your data and your body material. We only put this code on your data and body material. We keep the key to the code in a safe place in the hospital. When we process your data and body material, we always use only that code. Even in reports and publications about the study, nobody will be able to see that it was about you.

Who can see your data?
Some people can see your name and other personal information without a code. This could include data specifically collected for this study, but also data from your medical file. These are people checking whether the investigators are carrying out the study properly and reliably. These persons can access your data:

- Members of the committee that keeps an eye on the safety of the study.
- An auditor who works for the LUMC
- National and international supervisory authorities.

These people will keep your information confidential. We ask you to give permission for this access. The Health and Youth Inspectorate can access your personal information without your permission.

For how long do we store your data and body material?
We store your data in the LUMC for 25 years. We also store your body materials in the LUMC. They will be stored for 25 years in order to be able to make new assessments related to this study in the course of this study. If no longer needed, we will destroy your body material.

What happens if there are coincidental findings?
It is possible that during the study we discover something that is important to your health. In that case, the investigator will contact your general practitioner (GP). You will then discuss what needs to be done with your doctor or specialist. The cost of this will fall under your own insurance policy. With the form, you give consent to inform your doctor or specialist.

Can you take back your consent for the use of your data?
You can take back your consent for the use of your data at any time. Please tell the investigator if you wish to do so. But please note: if you take back your consent, and the investigators have already collected data for research, they are still allowed to use this information. The investigators will destroy your body material after you take back your consent. But if assessments with your body material have been carried out, the investigator can continue to use the results.

We send your data to countries outside the European Union
In this study, we will also send your coded data and biological material to a country outside the European Union, namely the United States. The privacy regulations in that country are not the same as those in the European Union. However, we will ensure that your privacy is protected at an equivalent level.

Do you want to know more about your privacy?

- Do you want to know more about your rights when processing personal data? Visit www.autoriteitpersoonsgegevens.nl.
- Do you have questions about your rights? Or do you have a complaint about the processing of your personal data? Please contact the person who is responsible for processing your personal data. For the present, this is:
    - The LUMC, see Appendix A for contact details and website.
    - If you have complaints about how your personal data is processed, we advise you to first discuss the matter with the research team. For further privacy-related information, refer to the privacy statement of the LUMC on the LUMC website: see Appendix A. You can also contact the Data Protection Officer at the LUMC. Alternatively, you can submit a complaint to the Dutch Data Protection Authority.

Where can you find more information about the study?

You can find more information about the study on the following website: https://euclinicaltrials.eu/. After the study, the website may show a summary of the results of this study. You can find the study by searching for 'GACHA' (2025-524045-27-00)

11. Will you receive compensation if you participate in the study?

The tests and treatment for the study will not cost you anything. If you are eligible and you take part in this study, you will receive an reimbursement.

The reimbursement consists of

- €50,- per control visit/follow-up visit,
- €25,- per phone call control,
- €150,- for infection with malaria,
- a bonus of €100,- after the last follow-up visit.

The total reimbursements amounts to €1.450,-. For back-up study subjects the total reimbursement is €150,-. You do not receive separate compensation for travel costs.

If you are withdrawn from the study by the investigator due to a medical reason, you will receive the full reimbursement. If you quit the study before it is completed, you will receive less compensation. The compensation for taking part in this study should possible be declared to the Tax and Customs Administration as 'income from other work'. If necessary, ask the National Tax Administration (in Dutch: de Belastingdienst) for more information.

12. Are you insured during the study?

Insurance has been taken out for everyone who takes part in this study. The insurance pays for damage caused by the study. But not for all damage. You can find more information about this insurance and any exceptions in **Appendix B**. It also says who you can report damage to.

13. We will inform your general practitioner

The investigator will send your general practitioner a letter to let them know that you are taking part in the study. This is for your own safety.

14. Do you have any questions?

You can ask questions about the study to the research team. Would you like to get advice from someone who is independent from the study? Then contact the independent expert, dr. A.H.E. Roukens. She knows a lot about the study but is not involved in it.
You can find her contact details in **appendix A**.
Do you have a complaint? Discuss it with the investigator. Would you prefer not to? Then please contact the complaints committee at the LUMC. **Appendix A** explains how you can do this.

15. How do you give consent for the study?

You can first think carefully about this study. Then you tell the investigator if you understand the information and if you want to take part or not. If you want to take part, fill in the consent form that you can find with this information sheet. You and the investigator will both get a signed version of this consent form.

Thank you for your attention.

16. Appendices to this information

A. Contact details
B. Information about the insurance
C. Overview of study visits and measurements
D. Highly effective contraception according to EMA Clinical Trials Coordination Group
E. Consent form

Appendix A: Contact details

Principal investigator

Prof. dr. M. Roestenberg

Leiden University Center for Infectious Diseases

Tel: 06-20942061

E-mail: vaccinonderzoek@lumc.nl

Independent expert

Dr. A.H.E. Roukens

Department of Infectious Diseases LUMC

Tel: 071-52662613

E-mail: A.H.E.Roukens@lumc.nl

Complaints

If you have a complaint about the study, you can contact Team Klachten of the LUMC via e-mail: patientenservicebureau@lumc.nl. You can also contact the Patiëntenservicebureau by phone: 071-5262989, during office hours. They will process your complaint according to the applicable regulations.

Privacy & rights

If you have questions about the protection of your privacy, you can contact the data protection officer at the LUMC (FG) via privacy@lumc.nl. For more information about your rights, you can contact the LUMC

Contact details LUMC

Albinusdreef 2

2333 ZA Leiden

Central telephone number: +31(0)71-5269111

For further information about your rights, please visit the website of the LUMC.

https://www.lumc.nl/12367/Deelnemers-wetenschappelijk-onderzoek/

Appendix B: Information about the insurance

The LUMC has taken out insurance for everyone who takes part in the study. The insurance pays for the damage you have suffered because you participated in the study. This concerns damage you suffer during the study or within 4 years after your participation in the study has ended. You must report damage to the insurer within 4 years.

Have you suffered damage due to the study? Please report this to this insurer:

The insurer for this study is:	
Name:	Centramed
Address:	Maria Montessorilaan 9, 2719 DB Zoetermeer
Telephone:	+31 (0)70-3017070
E-mail:	info@centramed.nl
Policy number:	624.530.305

The insurance will pay maximum €650,000 per person and €5,000,000 for the whole study (and €7,500,000 per year for all studies by the same client).

Please note that the insurance does **not** cover the following damage:

- Damage due to a risk about which we have given you information in this sheet. But this does not apply if the risk turned out to be greater than we previously thought. Or if the risk was very unlikely.
- Damage to your health that would also have happened if you had not taken part in the study.
- Damage that happens because you did not follow directions or instructions or did not follow them properly.
- Damage to the health of your children or grandchildren.
- Damage caused by a treatment method that already exists. Or by research into a treatment method that already exists.

These provisions can be found in the 'Besluit verplichte verzekering bij medisch-wetenschappelijk onderzoek met mensen 2015' ('Medical Research (Human Subjects) Compulsory Insurance Decree 2015'). This decision can be found in the Government Law Gazette (https://wetten.overheid.nl).

Appendix C: Overview of study visits and measurements

Day	Location/Time & duration	Activity
Screening visit	LUMC (by appointment), duration: 1 – 1.5 hours	Explanation about the study and possibility to ask questions. The informed consent form will be signed. You will be asked about your age, sex, body weight and height. Medical history of participant and of participant' close relatives will be collected. The following tests and assessments will be carried out: - Temperature, blood pressure, heart; - Physical examination; - Electrocardiogram (ECG); - Blood sampling and blood examination; - Urine sampling for drug test.
Study day 1: Control visit (day before infection with malaria)	LUMC, between 7:00 en 8:30 in the morning, duration: 15 minutes	The following tests and assessments will be carried out: - Temperature; - Blood sampling and blood examination; - Only for women: pregnancy test; - Assessment of side effects; - Assessment of study diary.
Study day 2: **Infection with malaria parasites by 5 mosquito bites**	LUMC, duration: full day	Participants are exposed to malaria parasites by 5 moquito bites. The following tests and assessments will be carried out: - Temperature; - Assessment of side effects; - Assessment of study diary.
Study day 7 t/m 22: **Daily control visit**	LUMC, daily between 7:00 en 8:30 in the morning, duration: 15 minutes	The following tests and assessments will be carried out: - Temperature; - Only for women: pregnancy test; - Assessment of side effects; - Assessment of study diary.
Study day 25: Phone call visit	Participants are called, duration: 2-15 minutes	The following tests and assessments will be carried out: - Assessment of side effects; - Assessment of study diary.
Study day 29: **Control visit + treatment**	LUMC, between 7:00 en 8:30 in the morning, duration: 15 minutes	Participants are treated with Malarone[1] (treatment consists of four tablets a day, for 3 days). The following tests and assessments will be carried out: - Temperature; - Blood sampling and blood examination; - Assessment of side effects; - Assessment of study diary.
Study day 31: Phone call visit	Participants are called, duration: 2-15 minutes	The following tests and assessments will be carried out: - Assessment of side effects; - Assessment of study diary.
Study day 32: Control visit	LUMC, between 7:00 en 8:30 in the morning, duration: 15 minutes	The following tests and assessments will be carried out: - Temperature; - Blood sampling and blood examination; - Assessment of side effects; - Assessment of study diary.

Study day 36: **<u>Control visit + end of study</u>**	LUMC, between 7:00 en 8:30 in the morning, duration: 15 minutes	The following tests and assessments will be carried out: - Temperature; - Blood sampling and blood examination; - Assessment of side effects; - Assessment and collection of study diary.
Study day 92: Follow-up visit	LUMC, duration: 15 minutes	The following tests and assessments will be carried out: - Blood sampling and blood examination.
Study day 183: Follow-up visit	LUMC, duration: 15 minutes	The following tests and assessments will be carried out: - Blood sampling and blood examination.

[1] When a participant develops malaria earlier, it will be treated on the same day with Malarone.

Appendix D: Highly effective contraception according to EMA Clinical Trials Coordination Group

- Combined hormonal contraceptives (estrogens and progestogens) that suppress ovulation:
    - Birth control pill (with the exception of the so-called ‘mini pill’ which only contains progesterone)
    - Administration via the skin or in the vagina
- Contraception that only contains progesterone but does suppress ovulation
- IUD (both hormonal and copper IUD)
- Vasectomy in partner
- Bilateral tubal ligation
- No (heterosexual) sexual contacts

Appendix E: Informed consent form study subjects

Belonging to the study called “Long term protection against malaria after a single GA2 immunisation (GACHA)”:

- I have read the information sheet. I was able to ask questions. My questions have been answered well enough. I had enough time to decide if I wanted to take part.
- I know that taking part is voluntary. I also know that at any time I can decide not to take part in the study. Or to stop taking part. I do not have to explain why.
- I give the investigator consent to inform my general practitioner that I am taking part in this study.
- I give consent to give my general practitioner information about accidental discoveries made during the study that are important for my health.
- I give consent to collect and use my data and/or body material (blood). The investigators only do this to answer the question of this study as described in the subject information sheet.
- I give consent to take a picture of me during screening for identification during the study.
- I know that some people will be able to see all of my data to review the study. These people are mentioned in this information sheet. I give consent to let them see my data for this review.
- I know that my coded data and biological material will be sent to a country outside the EU (the United States), where EU privacy regulations do not apply. I am aware that an equivalent level of protection has been agreed for my data.
- For persons of childbearing potential: I know that I cannot get pregnant during the study.
- For persons of childbearing potential: The investigator discussed with me how I can best prevent becoming pregnant.

Please tick yes or no in the table below.

I give consent to ask me after this study if I want to participate in a follow-up study.	**Yes ☐**	**No☐**

- I want to take part in this study.

My name is (participant):

Signature:

Date (DD/MMM/YYYY) : ____ / _____ / _____ Time __ : __ (24h notation)

I declare that I have fully informed this subject about the study mentioned.

If any information becomes known during the study that could influence the subject's consent, I will let this subject know in good time.

Investigator name (or their representative):

Signature:

Date (DD/MMM/YYYY) : ____ / _____ / _____ Time __ : __ (24h notation)

The participant will receive the entire patient information form, together with a certified copy of the signed informed consent form.