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PARTICIPANT INFORMATION SHEET

The PCV15/PCV20 Study

Full title: Evaluation of higher valency pneumococcal vaccines (PCV15/ PCV20) compared to PCV13 given in homologous schedules at 3 months and 12 months (“1+1” schedule) and 2 months, 4 months and 12 months (“2+1” schedule) in infants.



Decorative image: a baby laying on the floor, in crawling position

You are invited to enrol your 2-month-old baby to take part in a study which will help guide decisions on future changes to the UK National Immunisation Schedule in relation to *Streptococcus pneumoniae* (pneumococcus) vaccines.

Before you decide whether you are interested in taking part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. If anything is unclear or if you would like more information, please contact the study team.

St George's University Hospitals NHS Foundation Trust

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Summary:

- The study will evaluate protection provided by two new vaccines; PCV15 and PCV20 compared to PCV13 given in the current immunisation schedule.
- We aim to recruit 600 healthy children aged 8-10 weeks who have NOT yet received their first vaccinations.
- They will receive two doses of either PCV15, PCV20, or PCV13, or three doses of PCV20, as well as all their routine vaccines.
- Children receiving two doses of either PCV15, PCV20, or PCV13 will have five study visits, at ages 2, 3, 4, 12 and 13 months over a period of 11 months.
- Children receiving three doses of PCV20 will have six study visits at ages 2, 3, 4, 5, 12 and 13 months over a period of 11 months.
- Children will receive immunisations in their own home/at the trial site for all the visits till 12 months of age. Parents of children receiving two doses of either PCV15, PCV20, or PCV13 will be asked to fill in a symptom diary after the 3- and 12- month vaccination (on the day of vaccination and for the following 6 days). Parents of children receiving three doses of PCV20 will be asked to fill in a symptom diary after the 2, 4 - and 12- month vaccinations (on the day of vaccination and for the following 6 days).
- Children receiving two doses of either PCV15, PCV20, or PCV13 will have two blood samples taken at ages 4 months (4ml) and 13 months (6ml). Children receiving three doses of PCV20 will have two blood samples taken at ages 5 months (5ml) and 13 months (6ml). We will use a local anaesthetic cream to numb the skin for blood tests. Nasal samples using a soft paper will be taken at 3, 4 and 13 months of age for children receiving two doses of PCV13, PCV15 or PCV20. While, nasal samples using a soft paper will be taken at 2, 3, 5 and 13 months of age for children receiving three doses of PCV20.

Brief overview:

- Pneumonia, meningitis, and sepsis are serious (sometimes life-threatening) illnesses. They are particularly dangerous in young children, with babies under the age of two having highest risk of developing severe complications. They are all forms of pneumococcal disease, which is an infection caused by the bacteria *Streptococcus pneumoniae*, more commonly referred to as pneumococcal bacteria.
- The routine vaccine used currently in babies is PCV13 (Pneumococcal Conjugate Vaccine) that protects against 13 different types of pneumococcal bacteria and has proven effectiveness.
- However, there are over 90 different types of pneumococcal bacteria and we have seen an increase in disease caused by types not currently covered by the PCV13 vaccine.

What do we want to know? – To understand if the vaccines in the study (PCV15 and PCV20) can protect against more cases of serious disease in children and the adult population, than the existing vaccine PCV13.

Why has my child been invited to take part?

You have been approached because your child will shortly be due their routine immunisations and you live in an area where the study is being carried out.

If you have received this invitation through the post, it has been mailed to you either:

(i) by the Child Health Immunisation Service (CHIS) or other National Health Service equivalent databases within your local area. Please note: None of the study sites have been given your child's name or address through these databases,

or

(ii) direct mailout can also be done by the local site to potential participants identified using the local site's birth registry information. This data is held at your local site only and is not transferred between sites.

Taking part in this study is voluntary.

Does my child need to take part?

No. Taking part in this research study is voluntary and if you decide to say no, it will not affect your child's routine care in any way.

What will happen if I don't want my child to carry on with the study?

If you did take part, you are also free to change your mind and withdraw your child at any time without giving an explanation. If you did withdraw your child from the study and a blood sample(s) has already been taken, we would use the sample(s) and data we have collected from your child in our analysis up until the point you informed us that you wanted to withdraw. If consent was obtained for storing samples for future research beyond the end of the study period, we will ask if you wish to withdraw from this also. We would not collect any further samples, but we may ask you to allow us to make a follow up phone call to check for any side effects your child may have had during their time in the study or after withdrawal.

If you withdraw from the study before receiving all the vaccinations till 12 months of age, as per the UK immunization we will inform you to contact your GP surgery to complete your child's immunization schedule.

Whatever you choose, it is important that you are happy with your decision, and it is not the role of the study team to help decide for you. We will help present the details of the study and answer all your questions so you can make an informed decision.

Can my child take part?

Infants must be due to receive their primary immunisations, aged 2 months (+ 2 weeks) for first vaccinations. Children with some medical conditions will not be able to take part. These include impaired immunity or if your baby has had a severe allergic reaction to anything. Other serious conditions may also prevent you from being part of the study. We will discuss this with you in more detail before we ask you to sign a consent form at the first visit.

Sometimes your baby may be eligible to take part but due to things like a high temperature in the 24 hours before vaccinations visits, taking antibiotics or receiving any other vaccines in the 14 days prior to study vaccines, may result in needing to delay their vaccinations until they are well again.

What will happen to my child if they take part in the study?

If you decide you might like to take part in the study, our study team will be available to answer your questions and make an appointment to see you and your baby.

We will talk about the study in detail, answer any further questions you may have and if you are willing to proceed, we will ask you to sign a consent form.

Attending the visits will be either a doctor or a nurse and on the days that we are taking a blood sample.

We will give your baby all of their vaccinations as per the outline in table 2 and stay with you for at least 15 minutes after vaccination to make sure they are ok.

On the first visit we expect to be with you for about 1.5-2 hours. Further visits will take between 30 minutes and an hour.

You will be involved in the study for approximately 11 months in total. The study will continue until all participants at all sites around the UK have completed their final study visits.

The findings of the research will be written up in an academic publication and presented to the government to advise whether changes to the national immunisation schedule are advisable. Your child will not be identifiable in this publication.

Who is doing this study?

This study is being sponsored by the University of Oxford and coordinated by the Oxford Vaccine Group (OVG) which include scientists, doctors, nurses and play assistants who investigate infectious diseases and vaccines. St George's University Hospitals NHS Foundation Trust is one of several sites across the UK recruiting to the study.

Funding has been received from NISEC, the National Immunization Schedule Evaluation Consortium. The funder will have no influence on study decisions or the results from the study.

What are we researching?

In this study, we would like to learn more about two vaccines that protect against diseases caused by pneumococcal bacteria.

The current vaccine given to 3 month and 12-month-old babies in the UK is called PCV13, and as its name suggests it provides protection against 13 of these types. PCV13 has been very effective in reducing severe pneumococcal disease in children under 2 years of age since its introduction in 2010.

However, disease caused by different types of the pneumococcal bacteria not protected against by the PCV13 vaccine have increased, lessening the overall impact of the immunisation programme.

The vaccines we would like to research within this study are called PCV15 and PCV20. As their names suggest, they protect against 15 and 20 types of the pneumococcal bacteria.

In November 2022 the PCV15 vaccine was approved by the Medicines and Healthcare products Regulatory Agency for use in infants, children, and adolescents from 6 weeks of age to less than 18 years of age in the UK. PCV15 is not currently included in the UK national immunisation schedule.

The PCV20 vaccine has already been approved and in use in children in the USA since June 2023. In March 2024, the PCV20 vaccine was also approved by the European Medicines Agency for use in infants and children from 6 weeks of age to less than 18 years of age in the EU. Approval was on the basis of a 3+1 dosing schedule, it is not yet licensed for paediatric population to be used in the UK.

In this study for the PCV20 vaccine we will use either a 1+1 or 2+1 dosing schedule, so less doses of the vaccine than what is currently approved in the EU.

Compared to the current PCV13 vaccination given as a part of UK infant immunisation schedule, PCV15 and PCV20 may provide better protection to both children and the adult population against pneumococcal disease.

In addition, we would also like to look at the effectiveness of receiving three doses of PCV20 at 2, 4 and 12 months of age.

Will compensation be offered?

If study visits occur in the participant's homes, reimbursement will not be provided. . If the parents/legal guardians need to travel with the participant to attend St George's University Hospitals NHS Foundation Trust, they will be reimbursed for their travel expenses at a flat rate of £25 per visit attended.

If the parent/legal guardian withdraws consent for their child's continued participation in the trial or is withdrawn for any other reason, they will still be compensated for any trial visits they attended in a clinical setting.

What happens in the study?

The study is looking to recruit 600 healthy babies who;

- Are 8-10 weeks of age, healthy and were born after 37 weeks gestational age
- Have not yet received their first vaccinations

This study involves:

- Two doses of either PCV15, PCV20, or PCV13, or three doses of PCV20 along with their other routine vaccines as outlined in Table 2
- 5 visits over an 11-month period if receiving two doses of either PCV15, PCV20, or PCV13 or 6 visits over an 11-month period if receiving three doses of PCV20
- 2 blood samples taken at different time points
- 3 samples of nasal secretions with a small paper swab if receiving two doses of either PCV15, PCV20, or PCV13 or 4 samples of nasal secretions with a small paper swab if receiving three doses of PCV20
- Completion of a symptom diary after the 3 month and 12 month vaccinations (on the day of vaccination and for the following 6 days) if receiving two doses of either PCV15, PCV20, or PCV13
- Completion of a symptom diary after the 2, 4 month and 12 month vaccinations (on the day of vaccination and for the following 6 days) if receiving three doses of PCV20

Infants will be randomly assigned to one of four different treatment groups (as outlined in Table 1) after we have received written parental/guardian consent. If receiving two doses of either PCV 15, PCV 20, or PCV 13 they will receive PCV vaccinations at 3 and 12 months, and have two blood samples collected at 4 and 13 months of age and three nasal samples at 3, 4, and 13 months of age. If receiving three doses of PCV20 they will receive PCV vaccinations at 2, 4 and 12 months, and have two blood samples collected at 5 and 13 months of age and four nasal samples at 2, 3, 5, and 13 months of age. Further details regarding samples can be found on pages 6 and 7.

Table 1: General overview of study visits, vaccinations and sampling timelines

Visit number	1	2	3	3A	4	5
Participant age in months	2 months + 2 weeks	3 months + 2 weeks	4 months + 2 weeks	5 months + 2 weeks	12 months + 2 weeks	13 months + 2 weeks
Blood sample for Arms 1, 2, and 4	-	-	Up to 4mL		-	Up to 6mL
Blood sample for Arm 3	-			Up to 5mL		Up to 6mL
Nasal sample (mucosal lining fluid) for Arms 1, 2, and 4	-	Yes	Yes		-	Yes
Nasal sample (mucosal lining fluid) for Arm 3	Yes	Yes		Yes		Yes
Group 1 – 4	6:1 MenB Rotavirus	6:1 Rotavirus	6:1 MenB		MenB Hib/MenC MMR	
Group 1	-	PCV15	-		PCV15	-
Group 2	-	PCV20	-		PCV20	-
Group 3	PCV20	-	PCV20	-	PCV20	-
Group 4	-	PCV13	-		PCV13	-

The table 2 describes the vaccine schedule as a whole for this study. The short forms of the vaccine names used in the table are explained before the table.

Short forms of vaccine names used in table 2:

6:1 – Is a combined vaccine containing: diphtheria, tetanus, acellular pertussis (whooping cough), Haemophilus influenzae b, hepatitis B, and inactivated polio vaccines

PCV13: pneumococcal

Rotarix: rotavirus

MenB: meningococcal B

MenC/Hib: meningococcal C/ Haemophilus influenzae b

MMR: measles, mumps, rubella

Table 2: Current UK vaccine schedule versus study vaccine schedule

Age	Current UK schedule	Study vaccines
2 months	DTaP/Hib/HepB/IPV (6in1) Rotarix (oral) MenB	DTaP/Hib/HepB/IPV (6in1) Rotarix (oral) Men B PCV20 if Arm 3
3 months	DTaP/Hib/HepB/IPV (6in1) Rotarix (oral) PCV13	DTaP/Hib/HepB/IPV (6in1) Rotarix (oral) PCV13 OR PCV15 OR PVC20 if Arms 1, 2 or 4
4 months	DTaP/Hib/HepB/IPV (6in1) MenB	DTaP/Hib/HepB/IPV (6in1) Men B PCV20 if Arm 3
12 months	Hib/MenC MenB MMR PCV13	Hib/MenC MenB MMR PCV13 OR PCV15 OR PVC20

Randomisation

The arm that your child is allocated to is decided by chance, like tossing a coin. In this study, we will use a computer program to allocate the group and there will be a 25% chance that your child will enter a particular group.

The study is an open label study, this means you will be informed about the PCV vaccines your child will be given when allocated in any of the group. Neither you, nor the study team will be able to influence which vaccine your child is given.

Sample collections and diaries

Blood sample:

In order to understand the effect of the vaccines your child will have 2 blood samples. (See Table 1).

The blood samples will allow us to see how your child's immune system has responded to their vaccinations.

We will take up to 4mls of blood (less than a teaspoon) when your child is under 5 months , up to 5mls of blood when 5 months of age (arm 3 only) and up to 6mls of blood after they turn 1 year of age.

We will use local anaesthetic cream to help numb the skin prior to taking the blood samples. The cream blocks the nerve signals in the skin where it is applied and helps to reduce any pain. The study team will explain how to use the cream before the visits. The study team will have a maximum of 2 attempts when taking blood. If the first attempt is unsuccessful, it is your decision whether we have another attempt or not. If no blood sample is obtained, an additional visit (to attempt venepuncture again) may be rescheduled for another day within the visit timelines, with parental/legal guardian consent.

Nasal (Mucosal) fluid sampling:

We will also collect samples of nasal secretions at 3 of the study visits if receiving two doses of either PCV 15, PCV 20, or PCV 13. We will collect samples of nasal secretions at 4 of the study visits if receiving three doses of PCV20. This will be done using a paper nose swab, which looks like soft paper. This will be inserted up the nostril and then the outside of the nose is pressed gently closed with a finger, so it touches the passage of the nostril for 60 seconds. The procedure may tickle a bit but is painless. These swabs will give us information about how the immune system in the nose changes after vaccination.

Figure 1: a nasal fluid sampling swab - this is a paper like sampling swab that has a smaller end to take the sample, and a larger end to hold the swab.



Diary:

After your child's vaccinations at 3 and 12 months, if receiving two doses of either PCV 15, PCV 20, or PCV 13, we will ask you to fill in an electronic or paper diary for 7 days. After your child's vaccinations at 2, 4 and 12 months, if receiving three doses of PCV 20 we will ask you to fill in an electronic or paper diary for 7 days. This will record if your child has a temperature or any reactions following their vaccinations.

Participation in future research

If you have answered Yes to questions 12 and 13 in the Informed Consent Form you may be contacted about future ethically approved research studies for which your child may be suitable and about studies in the future that are related to this study. All contact in relation to such future participation in research will only come from this study team in the first instance. If you wish you can be removed from the register of participation in future research at any time.

Your contact details will be held securely, in a participant management database separate from the PCV15/PCV20 study clinical database on a password protected computer in the Oxford Vaccine Group accessible by delegated Oxford Vaccine Group Staff.

What are the possible side effects of the vaccines and of blood sampling?

Blood Sampling:

The blood sampling may be uncomfortable but will be performed by trained staff and anaesthetic (numbing) cream will be provided to reduce any pain. There may be some short-term bleeding and/or bruising following the blood sampling.

Vaccines:

During this study, most of the vaccines that your child will receive are the same as those that your GP or nurse would give (see table 2). With those vaccines, the side effects are the same for all children. It is expected that children may experience some redness and mild swelling where the injection is given. Fever, irritability, sleepiness or reduced sleep, reduced feeding, diarrhoea or a rash are often seen. These reactions are usually mild and short-lived. Much less frequently, children may develop a high temperature (>40 degrees) which resolves after a day. Very occasionally, infants may become pale, floppy and less responsive than normal (hypotonic-hypo responsive episode) following their vaccinations. This can occur immediately or up to 48 hours after vaccinations. If this does occur, it will normally resolve without long-term consequences and does not usually happen again with further doses.

Very rarely, children can also have allergic reactions. An immediate, severe allergic reaction (anaphylaxis) can result in a rash, swelling of the body and breathing difficulties. The study team will observe your child for 15 minutes following their vaccinations as this is the time when most allergic reactions are expected to happen. The study team members carry medicine to treat these reactions (adrenaline) and are trained to administer it should such a reaction occur.

Information on specific vaccines

With the **MenB** vaccine, there is a higher risk of your child developing a fever when compared with the other vaccines in the UK schedule. This is more common (~ 7 in 10 cases) when given at the same time as the other routine immunisations. Therefore, as per recommendations we will advise you to give you child 3 doses of paracetamol, 6 hours apart after they have received this vaccine at visits 1, 3 and 4.

The **Rotarix vaccine** is a weakened form of rotavirus itself and so can cause mild symptoms of diarrhoea, nausea and irritability.

The **MMR** will often have a delayed reaction and around 7 to 11 days after the injection your child may feel a bit unwell or develop a high temperature for 2-3 days.

PCV15

With PCV 15 vaccine it has been observed that infants and children from 6 weeks to less than 2 years of age receiving the vaccine might get some mild side effects to it which includes fever, irritability, drowsiness, tenderness at the immunisation site, and decreased appetite.

PCV20

As with PCV15, PCV20 also might cause some mild side effects including redness, swelling, pain at the immunization site, fever, loss of appetite, irritability and lethargy.

Are there any benefits to taking part?

By taking part in this study, your child will receive all their routine vaccinations up to and including 12 months of age in your own home, or in clinic. You will also have access to a 24- hour paediatric study doctor for the duration of the study.

If your child receives either PCV15 or PCV20 they will be immunized against more types of pneumococcal bacteria than if they had received the PCV13 only.

What will happen to information collected in the study?

Data Protection:

We will collect information about your child's health to assess if they would be able to take part in this study. Initially we use an online screening questionnaire. For those participants who proceed to take part in the study, the data from the screening questionnaire will be kept with their study records. For those who do not proceed to participate in the study, all answers from the screening questionnaire will be kept until the end of the study recruitment period and we will then be deleted.

Your child will be given a study number, which will be used on study paperwork and all samples. Any paper notes will be held securely at the study site. With your permission, we may need to obtain information from your child's medical records to confirm medical history or vaccinations received. We will inform your child's GP practice/health visitor that your child is taking part in the study and that we will be giving all the routine vaccinations up to and including 12 months of age. The services responsible for recording all childhood vaccines given in the UK will be informed of the vaccines your child has received in this study.

UK General Data Protection Regulation (GDPR) requires that we state the legal basis for processing information about you. Medical research is regarded as "a task in the public interest". The University of Oxford is the 'data controller' and is responsible for looking after your information and using it properly. We will be using information from you and your child's medical records, namely GP records, NHS England, CHIS and other central NHS registries to undertake this study.

We will use as little personally identifiable information as possible. We will store the research data and any electronic research documents with personal information, such as consent forms, securely in password protected computers within OVG with authorised access only, for up to 25 years after the end of the study, or as per national regulatory requirements. Your email address is required for the electronic diaries, for them to function. Only site research staff and sponsor data managers will have access to view your email address and you will need to consent to this. Your email address will be deleted at the end of the study when no longer required. It will not be possible to identify your child in any publication or report.

The St George's University Hospitals NHS Foundation Trust will use your and your child's name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your child's care, and to oversee the quality of the study. Individuals from the St George's University Hospitals NHS Foundation Trust and regulatory organisation may look at your child's medical and research records to check the accuracy of the research study. The only people in the St George's University Hospitals NHS Foundation Trust or University of Oxford who will have access to information that identifies you and your child will be people who need to contact you about the study, or the care of your child, or to monitor/audit the data collection process. The people who analyse the information collected and the samples will not be able to identify your child and will not be able to find out your child's name or your contact details. If you withdraw from the study, we will keep the information about your child that we have already obtained, including blood samples and symptom diary data, but if you prefer you can request for the samples to be destroyed (they may already have been analysed). We may contact you about future studies if you have indicated this on the consent form.

We will keep your contact details confidentially to inform you about the results of the research. Once the research has been published, we will only keep your child's date of birth and name, to allow us to

identify your child should you make an enquiry about the study. Files will be confidentially destroyed when storage is no longer required.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited so that the research is reliable and accurate. You can find out more about how we use your information by contacting the St George's University Hospitals NHS Foundation Trust either by telephone on 0208 725 2316 or by emailing PCV15-PCV20study@sgul.ac.uk.

Further information about your rights with respect to your personal data is available at <https://compliance.web.ox.ac.uk/individual-rights>. Contact details of the sponsor's data protection office: The Information Compliance Team, University of Oxford, Wellington Square Oxford OX1 2JD; data.protection@admin.ox.ac.uk.

What will happen to the samples collected in the study?

Blood and nasal samples collected at the visits will be transported to the laboratory in a cool bag, processed at St George's University Hospitals NHS Foundation Trust and frozen within 24 hours of collection to be stored at St George's University Hospitals NHS Foundation Trust. All frozen samples will be shipped to OVG laboratory. Blood samples will then be sent to other laboratories in the UK and Europe for analysis. Samples will be labelled with a number, not your child's name. No genetic analysis will be undertaken for this study. However, we may also ask you whether part of the blood or nasal samples remaining after the study tests have been done, may be stored in the Oxford Vaccine Group library of samples ("Biobank"). If you agree to this, we will provide you with the relevant information booklet and ask you to sign a separate consent form. If you decide to consent to Biobank, then storing samples for genetic analysis is an option. If you decide otherwise, your left-over samples will be destroyed after the end of the study. You can opt out of having samples stored in the Biobank and still take part in the study.

Who to contact if I have a concern or wish to complain?

If you wish to complain about any aspect of the way in which you have been approached or treated during this study, you should contact your local study team at 0208 725 2316 and PCV15-PCV20study@sgul.ac.uk. You may also contact the University of Oxford RGEA (Research Governance and Ethics Assurance) at RGEA.Sponsor@admin.ox.ac.uk.

The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the likely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary. NHS indemnity operates in respect of the clinical treatment which is provided.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.

If you wish to contact the PALS team please contact 020 8725 2453 and pals@stgeorges.nhs.uk.

What happens at the end of the study?

We will inform your GP practice and the CHIS when you complete (or withdraw from) the study. We will provide the study findings on our website; a summary of this will be sent to you with a link, to enable you to access the full information.

Who has reviewed this study?

Research Ethics Committee must approve all research studies of this sort. This project has been approved by Research Ethics Committee South Central - Hampshire A Research Ethics Committee (REC reference: 24/SC/0222). The Oxford Vaccine Group Patient and Public Involvement group has reviewed the main participant-facing documents associated with this study (study information booklet, consent form, lay summary, invitation letter and advertising materials).

What should I do now if I am interested in taking part?

You do not need to make a final decision straight away. If you decide for your child to take part in this study or have any questions, you can:

- Access information via our website <https://www.ovg.ox.ac.uk/studies/pcv/sgul>
- Contact the research team by the phone number or e-mail address given below.
- Complete the online screening questionnaire: <https://www.ovg.ox.ac.uk/studies/pcv/sgul>
- Complete the reply slip and post it to us using the pre-paid envelope provided with your Invitation letter

If your response reaches us after the study has finished recruitment, we will let you know. A postcard reminder may be posted to you by the Child Health Information Service, or another equivalent NHS database, as described above. If we do not hear from you after this, we will assume that you do not want to take part.

Thank you for taking the time to read this information sheet and considering being involved. Members of the study team will be happy to discuss the study with you and answer any questions you may have.

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Yours Sincerely

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