



Babies born Early Antibody Response to Men B Vaccination: BEAR Men B

Parent Information Sheet

In 2015 the UK became the first country in the world to introduce the meningococcal group B (Men B) vaccine into its routine schedule for infants. This vaccine provides protection against meningitis (infection of the lining of the brain) and septicaemia (blood poisoning) caused by a subgroup (group B) of the meningococcus germ. In the UK babies are offered this vaccination at 2, 4 and 12 months.

We are working with Public Health England (PHE) to compare two schedules of the Men B vaccine in babies who were born prematurely. One group of babies will receive the Men B vaccine according to the current schedule and the other group will receive an additional dose at 3 months.

Why is this study being performed?

In the UK, babies receive their vaccinations according to a standard schedule, irrespective of their gestation at birth. This policy is designed so that all babies are protected as early as possible from vaccine preventable diseases such as polio, diphtheria, tetanus, rotavirus, pertussis (whooping cough), *Haemophilus influenzae* type B, pneumococcal disease and now meningococcal B disease. The Men B vaccination was added to the UK schedule in September 2015 and there has been no research looking at whether the vaccine gives the same protection to babies born early as it does to those born at term. We want to compare two different schedules of Men B vaccination and see if one gives better protection to babies born prematurely. It is possible that an extra Men B vaccine dose (i.e. three doses in early infancy instead of two) will offer better protection for premature babies. This is what we are trying to find out through this study.

Why has my baby been chosen and does my baby have to take part?

We are approaching you because your baby was born at less than 35 weeks of pregnancy and has not yet received their first vaccinations. If you decide to take part in the study you will be asked to sign a consent form, and we will give you a copy to keep. You would be able to withdraw your baby from the study at any time and without giving a reason. If you do not wish your child to take part in this study or withdraw your baby from the study before the end, their care will not be affected in any way and your baby would be offered vaccinations according to the routine UK schedule.

What happens if my baby takes part?

After you have signed the consent form your baby will be randomly (by chance) assigned to one of two groups: one group will receive all recommended vaccines according to the standard UK schedule and the other will receive one additional dose of Men B vaccine at 3 months. There will be no other differences in the vaccines received. The diagram below shows the schedule of vaccinations and blood tests for this study:



Vaccine	Product names		Age (months)					
			2	3	4	5	12	13
DTaP/Hib/IPV/ Hep B	Infanrix hexa®		✓	✓	✓			
Rotavirus	Rotarix®		✓	✓				
PCV13	Prevenar13®		✓		✓		✓	
MCC/Hib	Menitorix®						✓	
MMR	Priorix®						✓	
4CMenB	Bexsero®	Group 1	✓		✓		✓	
		Group 2	✓	✓	✓		✓	
Blood tests						✓	✓	✓

In this study we want to compare the vaccine responses of premature babies who have received their vaccinations according to two different schedules and to do this we will take a blood sample from the babies at 5, 12 and 13 months. These time points have been chosen so that we can compare the response following the primary vaccinations and before and after the booster vaccination. A maximum of 3 mls will be taken on each occasion and a local anaesthetic cream and oral sucrose solution may be used to make the blood test as comfortable as possible.

What would I have to do?

If you agree for your baby to participate, you will be asked to sign a consent form. After every vaccination visit, you will be given a diary card to complete, which will be collected at the following visit. The diary card will be used to record daily temperatures and any redness or swelling that may occur around the injection site for up to 7 days after each vaccination. Your study doctor or nurse will explain how to fill in the diary. We will provide you with a telephone number to contact us at any time if you have any concerns about your baby during the study. We will also ask you to let us know by telephone if your baby has been unwell during the 7 days after immunisation, even if the illness seems unrelated to the vaccination. If you have to visit a doctor for the illness, we may contact them for further information. If your baby is still in hospital at the time of the vaccinations we will ask the nurses looking after them to provide us with some more detailed information for the first 48 hours after vaccination and for the remainder of the observation period the participant diary card will be used. We will request your permission for study staff to ask your GP for your contact details if we lose contact with you during the study.



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What are the risks with these vaccines?

Because the vaccines used in this study are exactly the same ones being used for routine immunisation of other babies in the UK, we do not expect the risk to be any different than with the routinely given vaccines. As with all vaccinations, however, there may occasionally be some redness and/or swelling at the injection site and fever. Fever is a side effect particularly associated with the Men B vaccination and we will give you advice about steps you can take to try to prevent this. Some babies have been reported to feed less, be more irritable and cry more than usual after vaccinations. Severe allergic reactions, such as anaphylaxis, are extremely rare but can occur with any vaccine. Your baby would be observed for 20 minutes following each immunisation and the study staff are specifically trained and equipped to deal with this in the extremely unlikely event that it did occur.

What are the other possible disadvantages of taking part?

Blood tests may be uncomfortable for infants but we will try to minimise this by offering a local anaesthetic cream if appropriate to numb the skin before taking the blood sample.

What are the possible benefits of taking part?

We will check the antibody response your baby makes to the Men B vaccine. If we find that your baby has not made a sufficient response to the Men B vaccination they will be offered a booster. Unless your baby is an in-patient at the time of the vaccinations you will have the choice of coming to a clinic or for us to come to your home to give the vaccinations and take the blood samples. If you attended at the local site, your travel expenses would be paid up to a cost of £10. You will have 24 hour telephone access to a member of the study team if you have any concerns about your baby's vaccinations.

What happens when the research stops or if new information becomes available?

Before the study ends, we will tell you your baby's blood test results and whether your baby has adequately responded to the vaccines. If new or relevant information becomes available during the course of the study, we will inform you as soon as possible.

What if there is a problem?

St George's, University of London has agreed that if you are harmed as a result of your participation in the study, you will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention or procedures your baby received during the study. These special compensation arrangements apply where an injury is caused to your baby that would not have occurred if your baby was not in the trial. These arrangements do not affect your right to pursue a claim through legal action.

What if you wish to complain about the trial?

If you wish to complain, or have any concerns about the way you have been treated during this study, then you can talk to the BEAR Men B research team who will do their best to answer your questions or concerns (contact details at the end of Part 2). The National Health Service complaints mechanisms are also available to you: Patient Advice and Liaison Services (PALS), Oxford University Hospitals NHS Foundation Trust Tel: 01865 221473, email PALS@ouh.nhs.uk. If you are still not satisfied with the response, you may contact: The Sponsor Joint Research and Enterprise Office at St George's: 0208 725 4986.



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Would my baby's participation in the study be kept confidential?

Personal data collected will include your baby's name, date of birth and address as well as your contact details and results of the blood tests and medical records. This information will be stored on secure password protected NHS or University computers. The only people with access to this information will be employees of the hospital where your baby was born, the study team, your GP, the Department of Health or regulatory authorities who may wish to check the study is being carried out within the appropriate guidelines. The data will only be used for the purposes of this study and any data released outside the above group will not contain any information that could be traced back to your baby. You have the right to obtain access to data relating to your child. If you wish to obtain any information, please contact us on the numbers listed below.

What would happen to any samples from my baby?

We will test the blood samples to check your baby's level of immunity against the Men B vaccine and we may also test antibody levels against other diseases. At the end of the study any remaining blood samples will be destroyed unless you provide your specific permission on the consent form to allow us to use any of the extra samples for future ethically-approved research studies looking at how vaccines work. All extra samples will be anonymised so that it will not be possible to link the results of any extra tests back to your baby. Please remember that your baby's participation in this study does not depend on whether you allow or don't allow us to use the remaining blood sample.

What would happen to the results of the research study?

We will write to you at the end of the study to inform you of our findings. This will be around 12 months after the end of the study. This may be some time after your child's participation in the study has ended. We will retain your contact details in a secure database at the local site to enable us to contact you. We plan to publish the results in a medical journal so that other doctors can learn about the findings of the study. If you wish, you will also be sent a copy of the published research.

Who is organising and funding the research?

The study is funded by Meningitis Now and GlaxoSmithKline (GSK) and is sponsored by St. George's, University of London. This study has been reviewed and approved by Yorkshire & The Humber- Sheffield Research Ethics Committee and by the NHS Health Research Authority.

Further information

If you have any questions, or would like further information please contact:

BEAR Men B Study Team

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Website: www.ovg.ox.ac.uk/recruiting-studies

We do hope that you and your family will take part in this study. Your contribution would be an important step towards the continual improvement of vaccine policy in the UK and would provide important information that should help us know what the best vaccination schedule should be for premature babies born in the future.

Thank you for reading this leaflet and thinking about taking part in the study.