



Clinical Trial Information and Authorization Form
30Jun2009

Sponsor: Vaccine Evaluation Center, Vancouver, BC

Funding: Canadian Institutes of Health Research

Principal Investigator: Dr. Scott Halperin, Pediatric Infectious Diseases, IWK Health Centre

Co-Investigator: Dr. Joanne Langley, Pediatric Infectious Diseases, IWK Health Centre
Dr. Shelly McNeil, Infectious Diseases Specialist, QEII Health Sciences Centre

Research Title: Evaluation of Meningococcal C Conjugate Vaccine Programs in Canadian Children

Introduction

Your child is being invited to take part in the research study named above. Before you agree to have your child take part, it is important that you understand the purpose of the study, how it may affect your child, the risks and benefits of taking part and what you will be asked to do. Your child does not have to take part in the study. Taking part is entirely voluntary (your choice).

We refer to the process of giving you information as “informed consent”. This process starts with the initial contact about the study and continues until the end of the study participation. The research nurse or study investigator will be available to answer any questions you have. You may decide not to take part or you may withdraw from the study at any time. This will not affect the care you or your family members will receive from the IWK Health Centre in any way.

Why are the researchers doing the study?

In Canada, it is recommended that infants and children be immunized against meningococcal C

infection. Your child is due for this vaccine after his/her first birthday (12 months) but before turning 13 months of age. Provinces introduced this vaccine at various dosing schedules. For example, British Columbia has a two-dose schedule at 2 and 12 months, Alberta gives three doses at 2, 4 and 12 months and Nova Scotia gives one dose at 12 months.

The purpose of this study is to see if the protection level is stronger and/or lasts longer when the vaccine is given as 2-3 doses to infants as compared to one dose at 12 months of age.

How will the researchers do the study?

Approximately 465 healthy children 12 – 13 months of age will be participating in Canada between three centers. 155 will be recruited in the Halifax region under the direction of Dr. Scott Halperin, Pediatric Infectious Disease specialist at the IWK Health Centre. Dr. Joanne Langley and Dr. Shelly MacNeil are co-investigators in this study with Dr. Halperin.

Participants will be enrolled at 12 – 13 months of age but before they turn 14 months before the meningococcal vaccine is given. They will be given the vaccine and there will be blood samples taken to check for antibodies (protection level). There will be a blood sample collected before the vaccination and three times after the vaccination at approximately 13 months of age, 3 years and 5 years.

What will I be asked to do?

Participation in this study will involve four visits with study staff over a 4-year period. During the first visit, the information and authorization form will be explained to you. We will give you a chance to read the form and ask questions before signing that you agree to have your child take part in the study. You will be asked questions about your child’s health to make sure there are no factors that would not allow your child to be able to participate in the study. We will need a history of your child’s immunization to ensure all vaccinations recommended were given to your child and make sure that he/she has not received the meningococcal C vaccine.

Once the authorization form is signed, we will review your child’s medical history and measure your child’s length, weight, and temperature. A blood sample of approximately one teaspoon will be taken from your child’s arm. Following this, the routine meningococcal C conjugate vaccine will be given in the muscle of your child’s arm. This is the same vaccine your child would receive from your family doctor. We will also give the other routine vaccines your child is due to receive at this time (MMR and chickenpox). You will be asked to stay for 15 minutes so we can watch your child after the vaccines are given.

You will be asked to bring your child back in 4 weeks and again at age 3 and 5 years of age for blood samples. You will be contacted either by phone or will receive a card in the mail between the 3 and 5 year visits as a reminder to let us know if you move or change your phone number. See the table below for a summary of the study visits as well as an estimated time for each visit.

Visit 1	Visit 2	Visit 3	Visit 4
- Information and Authorization	- Reconfirm consent - Verify eligibility	- Reconfirm consent - Verify eligibility	- Reconfirm consent - Verify eligibility

<ul style="list-style-type: none"> - Health questions to confirm eligibility - Height, weight, temp./ medication history - Blood sample - Vaccination Neis Vac -C® vaccine Other routine 12-month vaccination - 15 min observation - Book Visit 2 	<ul style="list-style-type: none"> - Review Health issues - Blood sample - Twinrix courtesy vaccine, with boosters at 14 months and 2 yrs of age (no follow-up required). 	<ul style="list-style-type: none"> - Review health issues - Blood sample 	<ul style="list-style-type: none"> - Review health issues - Blood sample
Time 1.5 h	30 min	30 min	30 min

In addition, we will offer your child Twinrix vaccine as a courtesy in appreciation for your study participation. Twinrix protects against Hepatitis A and B. It is given as a series of three vaccinations. These will be given at approximately 13 months, 14 months and 19 months of age. The visits at 14 and 19 months are extra visits in addition to the four scheduled study visits. This vaccine is optional and your child can take part in the study without receiving the Twinrix vaccine. It is being offered as a courtesy only, not as part of the study.

What are the burdens, harms and potential harms?

The meningococcal C vaccine being used in this study is a licensed vaccine that has been proven to cause few reactions and to produce good protective levels in the blood. The most common reactions seen for the vaccine have been redness, swelling and soreness at the needle site. Other general reactions have included mild to moderate fever, irritability, decreased appetite, sleepiness, vomiting or diarrhea. As with any other vaccines or drugs, your child could experience a very rare allergic reaction. It is possible there may be other reactions that have not been seen before. Should this happen, Dr. Halperin or another doctor will see your child and you will be given advice about any necessary medical treatment.

The blood tests that will be done cause momentary pain and sometimes a bruise. A patch called EMLA can be applied over the vein where the blood will be taken to numb the skin and decrease the pain. The blood will be tested for protection levels against meningococcus C. Routinely, blood is not drawn after vaccination. This is being done to check protection levels of your child. If the protection level is low a booster may be offered to your child. If your child does require a booster due to low protection levels, he/she will not continue with any further follow-up blood testing as part of the study. Since he/she will be boosted due to a low level, the follow-up testing would not be accurate in comparison to other children in the study.

What are the possible benefits?

There is no medical or other benefit to your child as result in this study. The blood testing is not usually done with routine vaccinations. If your child does not show protective levels after vaccination, a booster dose would be offered free of charge. Even though there is no proven benefit to your child, other infants and young children may

benefit from what is learned in this study.

We will offer a courtesy vaccine called Twinrix a vaccine for hepatitis A & B normally Hepatitis B is given in grade 4, this will provide early protection and also include protection of hepatitis A.

What alternatives to participation do I have?

Your child does not have to participate in this study to receive vaccines to protect your child from these illnesses. The regular Meningococcal® vaccine are available from your family doctor free of charge at 12 months of age. If you want your child to receive the Twinrix vaccine it can be purchased through your family doctor for approximately \$30.00/dose (3 required).

Can I withdraw from the study?

Participation in this study is entirely voluntary (your choice). You may decide not to enrol your child or you may withdraw your child from the study at any time. This will not affect your child's care by his/her doctor or at the IWK Health Centre in any way or result in any penalty or loss of benefits. Your child's participation in the study may be ended if, in the opinion of the study staff, it is not safe or reasonable for him/her to continue. Data and blood collected prior to withdrawal will be analysed as per the study guidelines. No further data or blood will be collected after withdrawing from the study. The investigators have the right to end the study at any time without your consent.

Will the study cost me anything and if so, how will I be reimbursed?

Participation in this study will not result in any expenses to you or your child. In recognition of your time commitment to the study and transportation costs, you will receive \$25 for each visit completed. The cheque will be mailed to you approximately four weeks after Visit 2 (\$50.00), Visit 3 (\$25.00) and Visit 4 (\$25.00). The extra visits done to receive the courtesy Twinrix vaccine are not considered study visits. They are being done to provide this extra vaccine to your child. You will be asked to sign a form saying that you have received the payment and that it is your responsibility to declare it on your income tax return. If you withdraw early from the study, payment will be prorated based on the number of completed visits. You should also know after the study is completed, participants do not receive any further financial reimbursement.

Are there any conflicts of interest?

There are no known conflicts of interest on the part of researchers and/or IWK. The Vaccine Evaluation Center, with funding from Canadian Institutes of Health Research will cover the costs of conducting the study at the IWK Health Centre. The study staff will be compensated for the time to conduct the study.

What about possible profit from commercialization of the study results?

There will be no commercial benefit to the sponsor, funder, investigator or participant from this study.

How will I be informed of study results?

The overall study results can be made available to you once the study is completed and reported. This may take at least a year after the whole study is finished. The results will be mailed to you if you want to receive them. You will be asked to initial the last page of this form indicating if you wish to receive the results. It will be important that you notify us of any change in your address, so we are able to contact you with study results.

How will my privacy be protected?

Any information that is learned about your child or family will be kept as confidential as possible within the limits of the law. Study information sent to the sponsor, Vaccine Evaluation Center, will not include information that directly identifies your child; instead, a code number is assigned to the study information. This coded information may be reported to the sponsor, the Canadian Health Products and Food Branch (HPFB), the United States Food and Drug Administration (FDA) and other regulatory agencies. Study staff will have access to your child's study records that contain information that directly identifies your child. In addition, these records may be shown to representatives of the Vaccine Evaluation Center, the regulatory authorities in Canada or the US and the IWK Research Ethics Board as part of an audit. In addition, if you were to report an illness or injury or hospitalization of your child we may need access to your child's health record (like hospital chart) to collect information about the illness or injury.

If the results of the study are published in the medical literature, the publication will not contain any information that would identify your child. Study records will be stored in a locked area at the IWK and will be kept for 27 years, which meets or exceeds the requirements of the IWK Research Ethics Board, regulatory agencies in Canada, the United States and the study sponsor.

What are my research rights?

If your child becomes ill or injured as a direct result of participating in this study, necessary medical treatment will be available at no additional cost to you. Your signature on this form only indicates that you have understood to your satisfaction the information regarding your child's participation in the study and agree to have your child participate as a subject. In no way does this waive your legal rights nor release the investigator, the research doctor, the study sponsor or involved institutions from their legal and professional responsibilities.

Your child's participation in the study may be ended if, in the opinion of the study staff, it is not safe or reasonable for your child to continue. The sponsor also has the right to end this study at any time. If the study is changed in any way that would affect your decision to continue to have your child participate, you will be told about the changes and you may be asked to sign a new authorization form.

If you have any questions at any time about this study or about research in general, you may contact the Research Office of the IWK Health Centre at 470-8765, Monday to Friday between 9 am to 5 pm.

What if I have study questions or problems?

If you have any questions, please call the study nurse _____ at _____ or the study doctors at 470-8141. You may also call the study coordinator, Pam MacIntyre at 470-8948, Monday to Friday between the hours of 9am and 5pm. In an emergency, you may also reach your study nurse or Dr. Halperin at any time by calling the IWK Health Centre at 470-8888, and ask for them to be paged. In the event that participation in this

study has led to any reactions or serious events, please contact the study nurse or doctor as soon as possible. The matter will be reviewed with you by one of the study doctors, who will assist you in obtaining appropriate medical care.

Future Use Of Specimens

Left over blood samples will be stored for possible future testing for this study only for 10 years.

Contact for future studies

You will be asked if you are willing to be contacted for future studies by our staff for either your children or for you. If you do wish to be included we will collect information needed to contact you in the future. This information would include name, address, phone number and date of birth, which we would store in a secure area. If you wish to be contacted, we will ask you to initial the signature page of this form to indicate this. We will collect this information at the 13-month visit, when we will reconfirm you still wish to do this. If you indicate you agree today and change your mind later, it is not a problem and will not impact your care in any way.

Study Title: Evaluation of Meningococcal C Conjugate Vaccine Programs in Canadian Children

Participant ID: _____

Participant Initials: _____

Parental or Guardian Authorization - I have read or had read to me this information and authorization form and have had the chance to ask questions which have been answered to my satisfaction before signing my name. I understand that I have the right to withdraw my child from the study at any time without affecting my child's care in any way. I have received a copy of the Information and Authorization Form for future reference. I freely agree to have my child participate in this research study.

Name of Participant (Print)

Name of Parent/Guardian (Print)

Signature of Parent/Guardian

Date: _____ Time: _____

- 1) I would like to receive a copy of individual and study results when available.
 Yes No _____(Initial)
- 2) I would like the study staff to inform my doctor of my child's participation in the study
 Yes No _____(Initial)
- 3) I agree to be contacted and given information about future studies. Yes No _____(Initial)
- 4) I agree for any left over blood samples to be used for further testing if required for this study
 Yes No _____(Initial)

STATEMENT BY PERSON PROVIDING INFORMATION ON STUDY

I have explained the nature and demands of the research study and judge that the Parent/Guardian named above understands the nature and demands of the study.

Name (Print): _____ Position: _____

Signature: _____ Date: _____ Time: _____

STATEMENT BY PERSON OBTAINING AUTHORIZATION

I have explained the nature of the authorization process to the person authorized and judge that they understand that participation is voluntary and that they/their child may withdraw at any time from participating.

Name (Print): _____ Position: _____

Signature: _____ Date: _____ Time: _____