PATIENT INFORMATION LEAFLET

Meningitis vaccine follow up study

Full Study Title:
An observational follow up study of a phase II/III, open label, randomised study of the safety, reactogenicity and immunogenicity of a single dose of meningococcal ACWY conjugate vaccine (Menveo, Glaxosmithkline or Nimenrix, Pfizer) in adolescents who were primed with Meningitec, Menjugate or Neisvac-C during preschool vaccination.

Why have I been contacted?
You took part in a study of meningitis vaccines as a young adult. We are contacting all those who took part in this study as we are looking at how long the protection offered by these vaccines lasts. As someone who took part, you offer a unique opportunity to see how your immune response to the vaccine has changed over time and from this assess how well the vaccine protects against different strains of meningitis some years later. This will help guide the national immunisation schedule in the future.

What will be involved if I take part in the study?
The study will involve providing a single blood sample of 8ml (less than two tablespoons). Anaesthetic cream will be offered prior to your appointment to minimise any discomfort.

We will inform your GP that you are taking part in the study with your consent to do so. A single blood test will be needed and your nurse will be able to advise on whether this should be carried out in the GP surgery or in your own home, for example if you are at university and no longer registered at a GP in Hertfordshire or Gloucestershire.

If your blood test shows a low level of antibody to type W that suggests you may not be protected against disease, you will be offered an extra dose of vaccine. We will send you a letter to let you know your result and if an extra dose is indicated, your vaccine research nurse will telephone you to discuss this.

Are there any potential benefits or risks if I take part?
The blood test may cause slight discomfort and there may be some pain or bruising at the site where the blood is taken. However anaesthetic cream will be offered to minimise discomfort and the procedure will be carried out by an experienced research nurse.

What will happen to any leftover samples?
Once the tests for this study are complete, there may be small amounts of blood left over from the sample taken from you. We would like to be able to use this, once coded, to help us understand better how vaccines work. You will be asked to consent to this separately as your participation is not dependent on this.

What data and confidentiality safeguards are in place?
Under the data protection laws, you have a right know how your personal data from this trial will be used so that you understand exactly what information will be collected and who will have access to it. Personal data may include your name and address as well as results of the blood/ tests, and medical records. The only people with access to this information will be employees of Public Health England who are directly involved in the study 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 be anonymised, including to the PHE laboratory, which will be processing the blood samples.

Data will be stored in secure Public Health England facilities and will be disposed of within clinical trial guidelines after the appropriate time period which may be a number of years.

Complaints
If you have any concerns about any aspect of this study, you can contact the Vaccine Research Nurse or the study organisers (see details below), who will do their best to answer your questions. If you remain unhappy and wish to complain formally then you can do this through the National Health Service Complaints Procedure, details of which can be obtained at www.nhs.uk or by phoning 0845 601 3012.

Harm
In the event of any claim for personal injury during the research which is due to someone's negligence you will have grounds for legal action for compensation against Public Health England but you may have to pay your legal costs. The National Health Service complaints mechanism will still be available to you. Where justified, an ex gratia payment for any non-negligent harm may be made.

You have the right to obtain access to personal data. If you wish to obtain any information, please contact us on the numbers listed on the following page.

Will any genetic tests be done?
No genetic tests will be carried out on your samples.

Who reviewed the study?

All research in the National Health Service is looked at by an independent group of people, called a Research Ethics Committee to protect the safety, rights, well-being and dignity of individuals. This study has been reviewed and given favourable approval by the XXX Ethics Committee - Reference XXXX.

What will happen to the results of the research study?

We will send all participants a summary of what the study finds. We plan to publish the results in a medical journal which will be accessible to the public (an access fee may apply with some journals). The results of the study will also be reported to the Department of Health to help with planning national vaccination programmes in the future. In any report or publication arising from this study, readers will not be able to identify any individual participant.

How do I enrol and what happens if I change my mind?
If you decide to enrol in the study after discussion with your study nurse, you will be asked to sign a consent form. Participation in this study is entirely voluntary and you would be free to withdraw at any time without giving a reason and with the assurance that your routine care would not be affected.

If you have any questions, you can ask your study nurse or contact the organisers, Dr Paul Turner and Dr Jo Southern on 02083276021.

Further information about our trials programme including links to the organisations reviewing research and the guidance we follow can be found at http://www.phe.gov.uk and typing clinical trials into the search bar.

We do hope that you will take part in this study. Your contribution would be an important step towards the continual improvement of vaccine policy in the UK. The study is funded by the Department of Health and we plan to publish the results in a medical journal.

Sticker with VRN name and contact details