

PATIENT INFORMATION LEAFLET

HPV Follow Up Study

Full Study Title: An observational follow up study of a randomised parallel group phase IV study to evaluate the duration of the immune response to vaccine and non-vaccine HPV types in UK adolescent females who received either Cervarix or Gardasil Human Papillomavirus (HPV) vaccines.

Why have I been contacted?

You took part in a study of Human Papilloma Virus (HPV) vaccines as a young adolescent. We are contacting all participants who took part in this study as we are looking at how long the protection offered by these vaccines lasts. As part of the group of young females who took part in this study, you offer a unique opportunity to study long term responses to vaccination at an age appropriate to the UK schedule, which has been less extensively studied. We will be able to look at how your immune response has changed over time and from this assess how well the vaccine protects against HPV types many years after it was received.

What will be involved if I take part in the study?

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 taken 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.

The study will involve providing a single blood sample of 8ml (less than a tablespoon). Anaesthetic cream will be offered prior to your appointment to minimise any discomfort. This blood sample will enable us to look at how well your immune system is able to respond to HPV types several years after you received the vaccine and therefore predict how long people are protected by the vaccine.

Are there any potential benefits or risks if I take part?

The blood sampling 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 experienced vaccine research nurses.

Information gained from this study will help to increase understanding of how long the protection offered by HPV vaccines lasts and will inform vaccination policy in the future.

There are no direct benefits to participants for taking part in this study.

What will happen to any leftover samples?

Once the tests for this study are complete, there may be small amounts of blood remaining from the samples taken from you. We would like to be able to use these samples, 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 02083276084.

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