

The ARTISTIC Trial

You signed a consent form between 2001 and 2003 to participate in the ARTISTIC trial, a randomised trial of HPV (Human Papillomavirus) testing in primary cervical screening.

HPV is a common virus which can affect the cervix. It is thought to be sexually transmitted. It does not produce any symptoms and can lie dormant for years, so there is no way of knowing how long it has been present in the cervix. Up to 70% of women who are, or have ever been sexually active have had this infection at some time in their life, and in most cases it is cleared up by the immune system. It has been shown that if this virus infection persists, it can be associated with pre-cancerous changes in the cells of the cervix, resulting in an abnormal smear test result later on. HPV testing may identify abnormal cells not detected by the smear test, or it may indicate the need for another smear sooner than the normal 3-5 year interval for smears.

We have now obtained additional funding from our sponsor, the Health Technology Assessment Programme, to enable us to extend the ARTISTIC trial until 2009. To enable us to access your screening results

and HPV test your smear sample, we require your consent.

What will I have to do if want to remain in the study?

Please sign the enclosed consent forms to say that you understand the trial, wish to participate and allow us to use the information collected - **all information given will be treated confidentially**. Return both consent forms to the Trial Office in the postage paid envelope, we will then send one to your GP practice and keep the other for our records. You will be reminded by letter when your next smear and HPV test are due and you can make an appointment for the test with your GP or Family Planning Clinic.

Your next smear test will be taken in the normal way, using Liquid Based Cytology (LBC), but will also be tested for Human Papillomavirus. In order to see how effective the HPV test is we need to compare a group of women in whom the HPV result is known with a group of women in whom the HPV result is not known.

You will keep the same trial number and remain in the same group (HPV result revealed or concealed) to which you were originally randomised. You will receive a result letter from the Trial Office as well as the Health Authority.

Do I have to continue to take part?

Continued participation in the trial is voluntary. If you decide not to participate, you will still have your smear taken in exactly the same way. This will not affect your treatment. Furthermore, if you re-consent to participate in the trial but wish to withdraw at any time, then you are entirely free to do so.

Smear takers will be provided with spare copies of the consent forms in case you have not already returned yours to the Trial Office. You can sign it when you attend for your next smear, or you can let them know that you wish to opt out of the trial.

What happens if I am in the group where the HPV result is revealed?

You will be told both your HPV and smear test result. If your smear is abnormal, you will be managed under current NHS guidelines, the same as if you were not participating in the study. If the smear is normal, but the HPV result is positive we will repeat the HPV test when your next smear test is due. In many cases the infection clears up on its own. If it is still positive, you will be referred for a colposcopy examination of the cervix to detect any possible underlying abnormalities.

N.B. This will replace the current arrangements whereby women who test HPV positive with a negative smear are recalled for an HPV only test after 12 months

What happens if I am in the group where the HPV test is not being revealed?

One quarter of the women who take part will not be told of their HPV result. If you are in the concealed arm of the trial, management of any abnormal results will remain exactly as it is under routine NHS Cancer Screening Programme guidelines. You will be notified of your smear result and informed of any follow up where required.

Are there any benefits in participating in this study?

By continuing to take part in this trial you will be assisting in providing evidence as to whether or not HPV testing picks up more abnormalities than the smear test alone. The implementation of HPV testing in the future might mean that those women with normal smears and negative HPV results would only need to attend for a smear say every 10 years. Before any changes can be made to the programme studies such as this one need to be carried out.

Finally, THANK YOU for your participation in the ARTISTIC trial so far, it has been very

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helpful. We hope that you will continue to participate, and if you have any queries, please don't hesitate to get in touch.

For further information please contact:

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The NHS has a central register which we are using to help us keep in touch with women in the study.

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A.R.T.I.S.T.I.C
A Randomised Trial In
Screening To Improve
Cytology

Information
Leaflet

