compass

Future directions
in cervical screening

VCS Foundation

Cancer Council NSW

A joint research initiative of VCS Foundation and Cancer Council NSW

The Compass Trial: Screening to Prevent Cervical Cancer

Cervical cytology versus a Test for HPV (Human Papillomavirus)

We now know that long term infection with certain types of Human Papillomavirus (HPV) is the main cause of cervical cancer. Overseas research has shown that a test for these HPV types is, in fact, a better cervical cancer screening test than the Pap smear.

In this trial we want to confirm that this is the same for women in Australia.

In the Compass trial, you will have a test taken from your cervix in exactly the same way as you would usually have a Pap smear except that the cells will be put into liquid rather than onto a glass slide. This liquid sample can be used to make a Pap smear or to do an HPV test.

Some women in this trial will have a Pap smear; some women will have a test for HPV. The Pap Smear is the test which has been used for cervical screening in Australia for over ten years, the HPV test is the new test being used in Australia from December 2017.

If the HPV test is negative, the likelihood of developing cervical cancer is so low that it is safe to leave the next screening test for 5 years. If the HPV test is positive there is a chance of having or developing abnormal cells on the cervix so further tests need to be done.

This trial is being conducted by the Victorian Cytology Service (VCS) and Cancer Council NSW.

PURPOSE OF THE TRIAL

The Compass Trial is comparing HPV testing to the Pap smear for cervical cancer screening.

The trial aims to confirm that HPV testing is as good as (and also if it is better than) the Pap smear at preventing the most serious grade of precancer or cervical cancer in women aged between 25 and 69. We will look at this in women who have been offered the HPV vaccine and women who have not been offered the HPV vaccine.

The HPV vaccine was available to all women aged 18-26 free of charge between 2007 and end of 2009. As we have now reached the target number for women born before 1st July 1980, we are now only recruiting women born on or after 1st July 1980 AND aged at least 25.

If you agree to take part in the study we will follow you and observe the results of your cervical screening tests for the next 5 years. Researchers will have access to your cervical screening results currently stored on the National Cancer Screening Register. The Compass Register will remind you when your next cervical screening test is due.

You are under no obligation to take part in this trial. If you think you would like to take part and then change your mind you can withdraw at any time by calling 1800 611 635.

If you choose to withdraw you will be sent a reminder for your next cervical screening test by your relevant Australian Jurisdictional register according to the National Cervical Screening Guidelines. All data collected as part of the Compass Trial will be kept permanently as part of your test record at the Compass Register and VCS Pathology. If you withdraw from the Compass Trial, researchers will not use your information in any future data analysis for the Compass Trial. For more information on how your data is stored please visit www.vccr.org/ privacy and http://www.vcspathology.org.au/women/privacy-statement

WHY AM I BEING ASKED TO TAKE PART IN THIS TRIAL?

You are being asked to take part in this trial because you are having a routine cervical screening test at a medical practice which has agreed to recruit women for the Compass Trial.

You can be part of this trial if you are:

- An Australian resident
- born on or after 1 July 1980 AND aged at least 25
- attending for a routine cervical screening
- not already enrolled in the Compass Trial Pilot Study

If you have symptoms which might suggest cervical cancer, you are not eligible for this trial.

Please read this information carefully and ask your health practitioner questions about anything you don't understand.

If you decide you want to take part in the Compass Trial, you will be asked to sign the consent form. By signing it you are telling us that you:

- Understand what you have read
- Agree to take part in the trial
- Agree to have the tests and treatments that are described; and
- Consent to the use of your personal and health information as described
- Consent to opting out of receiving correspondence from your local state or territory register and having your cervical screening follow-up managed on the Compass register hosted by VCS Foundation.

At the conclusion of your participation in the trial your complete screening records will be transferred to the National Cancer Screening Register (NCSR) unless you choose to opt of the NCSR.

PARTICIPATION IN COMPASS AFTER DECEMBER 2017.

Up until December 2017 women joining the Compass trial were randomly assigned to either;

- Cytology (the Pap smear), the test that women attending their GP clinic for cervical screening would have received regardless of whether they agreed to participate in the study.
- HPV DNA test, the new test which has been shown in international studies to be better for cervical screening.

From December 2017 the National Cervical Screening Program will change from offering women a Pap Smear every 2 years to a HPV DNA test every 5 years.

If you decide to join Compass after December 2017 you will still be randomly assigned to either of these technologies, however by participating in the trial you are agreeing to the chance of being randomized to have your cervical sample tested with cytology which is what has previously been recommended for screening in Australia), and being screened more frequently (every 2.5 years instead of 5).

The pap smear has been used in Australia since 1991 and has been proven to be very safe and effective at reducing the rate of cervical cancer. The HPV test is being introduced in place of the Pap test based on a broad range of scientific evidence. Compass is being conducted as there is no direct evidence comparing the pap smear to the HPV test in Australian women nor in cohorts of women who have been offered HPV vaccination.

For more information visit: **www.compasstrial.org.au**

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VCS Foundation and Compass acknowledges the support of the Victorian Government

VICTORIA State Government

WHAT DOES TAKING PART IN THE TRIAL INVOLVE?

In this trial we want to compare different cervical screening methods (HPV tests and Pap smears).

Your health practitioner will take your cervical screening test in exactly the same way as usual, but will put the cells in liquid instead of placing them on a glass slide. This sample (called liquid-based cytology or LBC) will be sent to the laboratory. At the lab your sample will be put in one of two study groups for testing. The groups will be randomly selected by a computer, so you cannot choose which group you are in.

Group 1: Women in this group will have a Pap smear made from the cells in the fluid.

- If your Pap smear is negative (no abnormal cells are seen) you will be asked to come back in **2 ½ years (30 months)**
- If minor cell changes are seen you will be asked to come back in **1 year**.
- If more serious cell changes are found you will be asked to **see a specialist**

Group 2: Women in this group will have an HPV test from the cells in the fluid.

- If your HPV test is negative you will be asked to return in 5 years

(Note: As part of the safety-monitoring arm there is the possibility that you will be recalled to have a Pap smear at 2 ½ years instead of 5 years)

- If the HPV test is positive you will be put into either group 2A or group 2B. We will use different methods of looking for HPV in each of these groups

Once your health practitioner has your results they will let you know what follow-up is required.

If you are asked to see a specialist he/she will do a colposcopy. This involves examining your cervix more closely with a magnifying instrument. If any treatment is needed the specialist will discuss this with you.

The Compass Register will remind you when your next test is due, generally by writing to you 3 months before the due date. We also ask that you provide your email and mobile phone number so that the Compass Register can contact you the next time your cervical screening test is due. You can still participate in the Compass Trial if you do not provide your mobile phone number or email.

For your health and safety it is very important that you follow all instructions about follow-up and treatment from your practitioner.

If at any stage you have any questions about the trial you can contact the study hotline on 1800 611 635.

A Data Safety Monitoring Board and a safety-monitoring arm will both make sure that the trial is conducted in a safe manner.

CERVICAL SCREENING RECORDS & FOLLOW-UP

Your cervical screening records will be transferred from the NCSR to the Compass register, hosted by VCS Foundation. Any subsequent cervical screening records will also be stored on the Compass Register.

The Compass investigators will opt you out of receiving correspondence from the NCSR on your behalf and you will be followed on the Compass Register for the duration of the trial. The Compass Register will remind you when your next cervical screening test is due.

At the conclusion of your participation in the trial your complete screening records will be transferred to the National Cancer Screening Register unless you choose to opt of the NCSR for ongoing follow-up.

POTENTIAL BENEFITS

In this trial:

- Women who have a negative Pap smear will not need to return for another Pap smear for **2½ years**
- Women who have a negative HPV test will not need to come back for cervical screening for up to **5 years**

POTENTIAL RISKS

An abnormal Pap smear result or a positive HPV test distresses some women. Make sure you discuss all results with your practitioner. For more information you can visit **www.compasstrial.org.au**

COST

There is no cost to you for participating in the trial apart from the usual cost for the medical consultation. You will not receive any payment for taking part in this trial.

CONFIDENTIALITY

Information collected for this trial will be kept strictly confidential, in accordance with privacy laws. Only authorised staff will have access to the study data which will be stored in a password protected database at VCS and Cancer Council NSW for the duration of the study and for a period of at least 10 years after the completion of the study.

Results from this trial will be published in a series of scientific papers. You and any information collected about you will not be identifiable directly or indirectly in any of these publications.

If you have any questions or concerns about this study, please do not hesitate to contact Compass on 1800 611 635 or email enquiry@compasstrial.org.au

WHO IS CONDUCTING AND PAYING FOR THE RESEARCH?

The trial is being carried out, and partially funded, by VCS in conjunction with Cancer Council NSW. Some of the funding for the study has been provided by Roche Molecular Systems, which manufactures the HPV test used in the study. Roche Molecular Systems was not involved in the design of the study protocol, which is the responsibility of the Co-Principal Investigators, and Roche Molecular Diagnostics will have no role in the analysis of the data and no control over publication of the results of the trial.

Compass-PLUS

Compass-PLUS is a research study conducted within the Compass trial. Should you choose to participate in the Compass trial, a CCNSW researcher may contact you at a later date to invite you to participate in Compass-PLUS.

Participation in Compass-PLUS would involve answering several question related to your experiences of cervical screening and about your well-being, your health and lifestyle.

You can still participate in the Compass trial even if you do not want to participate in Compass-PLUS.

FUTURE USE OF LEFT-OVER LBC SAMPLES

Participation in the trial means that researchers will keep the remainder of your LBC sample. This may be used for future research to look at different HPV tests or to assist in monitoring the impact of the HPV vaccine. Approval from the Ethics Committee will be obtained prior to performing these tests. You will not have access to these test results, as the samples will be used for research and programme evaluation only and not to make a diagnosis of a medical condition.

Some residual samples may also be provided to Roche Molecular Systems for the purpose of validating new HPV testing instruments. Only de-identified data will be provided to Roche Molecular Systems and no information that would allow you to be identified will be provided to Roche Molecular Systems. You will not have access to these test results as the samples will be used for quality assurance and regulatory requirements for the development of new HPV testing methods.

If you prefer that the remainder of your sample is not used for further research or for validating new HPV testing instruments then please indicate this by ticking the box on the consent form. The choice is yours and you can still participate in the Compass trial even if you don't want your left-over sample used as described above.

ETHICS APPROVAL

This study has been approved by the Bellberry Ethics Committee and the Royal Australian College of General Practitioners National Research and Evaluation Ethics Committee. Research and Ethics committees ensure studies are performed to the highest scientific standard and in such a manner that the privacy, sensitivities and rights of each person participating in the research are protected. If you have a complaint or would like to speak to someone who is not involved in the trial, you can contact the Research Governance Officer, Bellberry Limited, Phone: 08 8361 3222, Email: bellberry@bellberry.com.au

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