

INFORMATION SHEET

We are currently looking for 400 healthy female volunteers to participate in a research study. This is a randomized, international, double-blinded, controlled study using an approved human papillomavirus (HPV) vaccine and an investigational HPV vaccine. An Investigational Drug means that the drug has not been approved by Health Canada.

Human papillomavirus is found to cause 98% of all cervical cancers.

The study is being conducted at two sites in Vancouver, The Vancouver Coastal Health Research Institute (at Vancouver General Hospital) and The Women's Health Research Institute (at Children's and Women's Hospital).

The purpose of this study is to test the safety and effectiveness of a new investigational vaccine compared with the approved vaccine.

The duration of the study is approximately 42 months and you will have 11 clinic visits. At visits 1, 2, and 4, you will be given a vaccination. The study will involve questionnaires, blood tests, gynecological exams (including a Pap smear), pregnancy tests, body temperature, and the completion of a vaccination record.

Please review the following inclusion and exclusion criteria to determine if you are eligible to participate.

IF YOU ARE UNSURE OF OR DO NOT UNDERSTAND ANY OF THE FOLLOWING INCLUSION AND EXCLUSION CRITERIA, PLEASE CONTACT US AND WE WILL HELP TO CLARIFY THESE CRITERIA.

INCLUSION - You may participate in this study if you meet the following requirements:

For items with an asterisk (*), if you do not currently meet these inclusion criteria, the Day 1 visit may be rescheduled for a time when these criteria can be met.

1. Female, 16 years and 0 days to 26 years and 364 days.
2. Never had Pap testing OR has only had normal Pap test results.
3. Subject fully understands study procedures, alternatives and risks, and gives voluntary written informed consent.
4. Able to read, understand, and complete the vaccination report card.
5. Good physical health based on medical history, physical exam, and lab results.
6. Sexual history at the time of enrollment:
 - 1-4 male and/or female partners; OR
 - ≥18 with 0 partners but plans to become sexually active in first 3 months of study

Male partner is defined as someone with whom the subject has penile penetrative sexual intercourse. Female partner is defined as someone who has contacted, either by penetrative (with fingers or other objects) or non-penetrative means, the subject's genitalia during sexual activity.

7. *Has refrained from douching/vaginal cleansing and using vaginal medications or preparations for 2 full calendar days prior to the Day 1 visit (count back 3 numerical days).
Subject agrees to refrain from these activities for 2 calendar days prior to any future visit involving collection of study specimens.
8. *Subject has refrained from sexual activity for 2 calendar days prior to the Day 1 visit (count back 3 numerical days).
Subject agrees to refrain from these sexual activities for 2 calendar days prior to any future visit involving collection of study specimens
9. *Since the first day of the subject's last menstrual period through Day 1, the subject has not had sex with males or has had sex with males and used effective contraception with no failures.
The subject understands and agrees that during the Day 1 through Month 7 period, she should not have sexual intercourse with males without effective contraception.

EXCLUSION - You will not be able to participate in this study if any of the following applies to you:

For items with an asterisk (*), if you meet these exclusion criteria, the Day 1 visit may be rescheduled for a time when these criteria are not met.

1. History of an abnormal cervical biopsy result.
2. History of a positive test for HPV.
3. User of recreational or illicit drugs or a recent history (within the last year) of drug or alcohol abuse or dependence.
4. History of severe allergic reaction requiring medical intervention.
5. Known allergy to any vaccine component, including aluminum, yeast, or BENZONASE™ .
6. Currently immunocompromised or has been diagnosed as having a congenital or acquired immunodeficiency.
7. Subject has had a splenectomy.
8. Subject is receiving or has received in the year prior to enrollment immunosuppressive therapies.
Ask Study Nurse if you are unsure what these are.
9. Has received, or plans to receive, any immune globulin product or blood-derived product within the 3 months prior to the Day 1 vaccination, through Month 7 of the study.
10. *Subject has received non-replicating (inactivated) vaccines within 14 days prior to the Day 1 vaccination or has received replicating (live) vaccines within 21 days prior to the Day 1 vaccination.

11. Has thrombocytopenia or other coagulation disorder that would contraindicate intramuscular injections.
12. *Subject has donated blood, or plans to, within 1 week prior to the Day 1 vaccination, through Month 7 of the study.
13. Expecting to donate eggs during Day 1 through Month 7.
14. Concurrently enrolled in studies of investigational agents or studies involving collection of cervical specimens.
15. Has received a marketed HPV vaccine, or has participated in an HPV vaccine clinical trial.
16. Any condition, therapy, lab abnormality or other circumstance that might confound the results of the study, or interfere with participation for the full duration of the study.
17. Subject is unlikely to adhere to the study procedures, keep appointments, or is planning to relocate during the study.
18. *Subject has had a fever within the 24-hour period prior to the Day 1 vaccination (oral temp $\geq 37.8^{\circ}$ C).
19. Subject is pregnant.
20. *Subject has clinical evidence of gross purulent cervicitis.
21. *Subject is having menses.
22. Subject has a history of or clinical evidence at the Day 1 pelvic examination of HPV related external genital lesions) or vaginal cancer.
23. Subject does not have an intact cervix uteri or has more than one cervix uteri.

Visit Schedule:

Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11
Day 1	Month 2	Month 3	Month 6	Month 7	Month 12	Month 18	Month 24	Month 30	Month 36	Month 42

Reimbursement:

You will receive no payment for taking part in this study. However, at each visit, you will receive \$25.00 per visit to reimburse you for your personal expenses directly related to the study (e.g. travel, parking, etc).

Total reimbursement (11 visits X \$25 per visit) = \$275.00

**If you would like to participate in this study or receive additional information,
please contact the HPV Recruitment Centre**

**phone: (604) 875-2424, ext 4878
e-mail: HPVStudy@cw.bc.ca**