**Participant flow**

372 participants screened

Exclusions (n=62):

 37 Lost to Follow-up

 18 Withdrew Consent

 4 Moved

 2 Inadvertent Enrollment

 1 Died

296 had >1 antibody sample after 1st Vaccine Dose

(included in mITT analysis of antibody response)

310 received >1 vaccine dose

(included in analysis of safety)

198 met per protocol efficacy criteria

186 naïve to >1 of HPV 6, 11, 16, 18

(included in PPE analysis of seroconversion rate and antibody response)

Exclusions (n=14):

 7 Lost to Follow-up

 6 Withdrew Consent

 1 Died

224 Completed at least 24 months of follow-up

 47 Lost to Follow-up

 12 Study closed before 24 months of follow-up

 7 Withdrew Consent

 6 Moved

272 naïve to >1 of HPV 6, 11, 16, 18

(included in mITT analysis of seroconversion rate)

**Baseline characteristics**

Baseline demographic and clinical characteristics by population (participants ages 15+)

|  | Modified Intent-to-Treatn=310 | Per-protocoln=198 |
| --- | --- | --- |
| Age, years | 38 (32-45) | 39 (33-46) |
| Race  |  |  |
|  White | 111 (36) | 74 (37) |
|  Black | 135 (44) | 87 (44) |
|  Indigenous | 40 (13) | 21 (11) |
|  Other | 24 (8) | 16 (8) |
| Country of origin |  |  |
|  Canada | 156 (50) | 97 (49) |
|  Endemic Country | 124 (40) | 81 (41) |
|  Other | 30 (10) | 20 (10) |
| HIV risk factor |  |  |
|  Sexual contact | 219 (71) | 144 (73) |
|  Injection drug use | 47 (15) | 20 (10) |
|  Perinatal transmission | 22 (7) | 15 (8) |
|  Other | 31 (10) | 19 (10) |
| Years since HIV diagnosis  | 8 (4-13) | 9 (4-13) |
| Suppressed viral load at Baseline | 215 (72) | 143 (75) |
| CD4 Count at Baseline (cells/mm3) | 510 (376-695) | 520 (390-710) |
| Nadir CD4 Count (cells/mm3) | 230 (120-340) | 230 (110-325) |
| Number of Vaccine Doses |  |  |
|  3 | 277 (89) | 198 (100) |
|  2 | 14 (5) | 0 (0) |
|  1 | 19 (6) | 0 (0) |
| Body mass index (kg/m2) | 27 (23-31) | 26 (23-30) |
| Smoking Status  |  |  |
|  Never Smoked | 153 (50) | 101 (52) |
|  Current Smoker | 102 (34) | 54 (28) |
|  Previous Smoker | 49 (16) | 39 (20) |
| Have had intercourse ever  | 288 (95) | 183 (95) |
| Ever pregnant  | 258 (83) | 166 (84) |
| Ever given birth  | 229 (74) | 143 (72) |
| Currently Sexually Active  | 195 (63) | 115 (58) |
| Contraceptive use  |  |  |
|  Current hormonal contraception | 44 (14) | 31 (16) |
|  Usually or always use condoms | 125 (40) | 76 (39) |
| Number of Lifetime Partners  | 6 (3-13) | 5 (3-10) |
| At least 1 partner before baseline  | 175 (58) | 101 (52) |
| At least 1 new partner between screening and baseline  | 19 (6) | 10 (5) |
| Baseline HPV Positivity to qHPV types  |  |  |
|  At least 1 by serology, Antibody | 191 (62) | 121 (61) |
|  At least 1 by PCR, DNA | 49 (16) | 31 (16) |
|  At least 1 by serology or PCR | 200 (65) | 127 (64) |

**Outcome measures**

Seroresponsiveness of HIV positive women to the quadrivalent HPV vaccine. Seroresponsiveness is measured at 7 and 24 months post vaccine dose 1 in women originally seronegative to the specific HPV type, using the proprietary Merck cLIA assay, and is reported as geometric mean titres (GMTs) in relation to HPV type-specific seropositivity cutoff values.

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | **Per Protocol\*** | **Modified Intent-to-Treat\*\*** |
| **Month** | HPV Type | N | Above Cutoff | N | Above Cutoff |
| **7** | 6 | 102 | 101 (99%) | 112 | 111 (99.1%) |
|  | 11 | 150 | 148 (98.7%) | 163 | 160 (98.2%) |
|  | 16 | 108 | 106 (98.1%) | 118 | 116 (98.3%) |
|  | 18 | 141 | 132 (93.6%) | 154 | 141 (91.6%) |
| **24** | 6 | 82 | 76 (92.7%) | 111 | 103 (92.8%) |
|  | 11 | 113 | 106 (93.8%) | 147 | 136 (92.5%) |
|  | 16 | 87 | 85 (97.7%) | 120 | 116 (96.7%) |
|  | 18 | 106 | 71 (67.0%) | 142 | 95 (66.9%) |

\*PP= 3 doses of the vaccine within 1 year and serology within 60 days of final vaccine dose

\*\*mITT= originally seronegative for type and 1+ vaccine dose with f/u serology

**Adverse Events**

| *AE\_TYPE* | *AE\_CODE* | *Ever(n=     310)* | *After Dose1(n=     310)* | *After Dose2(n=     291)* | *After Dose3(n=     277)* |
| --- | --- | --- | --- | --- | --- |
| >=1 Reported |  | 111(35.8%) | 82(26.5%) | 56(19.2%) | 61(22.0%) |
| INJECTION SITE |  | 95(30.6%) | 70(22.6%) | 50(17.2%) | 49(17.7%) |
| INJECTION SITE | PAIN | 92(29.7%) | 67(21.6%) | 48(16.5%) | 45(16.2%) |
| INJECTION SITE | SWELLING | 18(5.8%) | 9(2.9%) | 7(2.4%) | 10(3.6%) |
| INJECTION SITE | REDNESS | 18(5.8%) | 12(3.9%) | 7(2.4%) | 10(3.6%) |
| INJECTION SITE | ITCHINESS | 7(2.3%) | 2(0.6%) | 3(1.0%) | 3(1.1%) |
| INJECTION SITE | ECCHYMOSIS | 1(0.3%) | 1(0.3%) | 0 | 0 |
| SYSTEMIC |  | 62(20.0%) | 37(11.9%) | 17(5.8%) | 30(10.8%) |
| SYSTEMIC | HEADACHE | 33(10.6%) | 20(6.5%) | 7(2.4%) | 13(4.7%) |
| SYSTEMIC | FATIGUE | 28(9.0%) | 19(6.1%) | 8(2.7%) | 11(4.0%) |
| SYSTEMIC | MUSCULOSKELETAL | 22(7.1%) | 12(3.9%) | 5(1.7%) | 7(2.5%) |
| SYSTEMIC | GASTROINTESTINAL | 14(4.5%) | 10(3.2%) | 2(0.7%) | 5(1.8%) |
| SYSTEMIC | FEVER | 12(3.9%) | 6(1.9%) | 3(1.0%) | 6(2.2%) |
| SYSTEMIC | HIVES | 6(1.9%) | 3(1.0%) | 1(0.3%) | 3(1.1%) |
| SYSTEMIC | REDNESS | 6(1.9%) | 2(0.6%) | 0 | 4(1.4%) |
| SYSTEMIC | DIZZINESS | 2(0.6%) | 0 | 1(0.3%) | 1(0.4%) |
| SYSTEMIC | ITCHINESS | 2(0.6%) | 2(0.6%) | 0 | 0 |
| SYSTEMIC\* | ENCEPHALOPATHY | 1(0.3%) | 1(0.3%) | 0 | 0 |
| SYSTEMIC | PSYCHOLOGICAL | 1(0.3%) | 1(0.3%) | 1(0.3%) | 0 |
| SYSTEMIC | RESPIRATORY | 1(0.3%) | 1(0.3%) | 0 | 0 |
| SYSTEMIC | SWEATING | 1(0.3%) | 0 | 0 | 1(0.4%) |

Adverse events in participant ages 15+. Participants were observed for 30 minutes after each vaccination and were called 48 hours post-vaccination to review any adverse events (AEs). All AEs were documented up to 30 days after each vaccine dose in a study diary. Serious adverse events (SAEs) were collected throughout the study through patient report and supplementary chart review.

\*only 1 SAE was classified as possibly associated with the qHPV vaccine. This participant developed encephalopathy 7 days after the first dose of the qHPV vaccine. This SAE resolved without clinical sequelae.