ORAL HPV PREVALENCE BY GENOTYPE AMONG MEN WITH HIV IN BRAZIL, MEXICO, AND PUERTO RICO

Rathwell J[1], Wilkin TJ[2], Villa LL[3], Schell MJ[1], Sirak B[1], Lazcano-Ponce E[4], Santana-Bagur J[5], Allen-Leigh B[4], Portillo-Romero A[4], Silva RC[6], Galan de Paula L[3], Mota G[3], Isaacs-Soriano K[1], Mello C[2], Sahasrabuddhe VV[7], Giuliano AR[1]

1.Moffitt Cancer Center; 2. Weill Cornell Medicine; 3. Faculdade De Medicina, Universidade de São Paulo; 4. Instituto Nacional de Salud Pública (INSP); 5. The University of Puerto Rico School of Medicine; 6. Centro de Referencia e Treinamento em DST/Aids; 7. Division of Cancer Prevention, U.S. National Cancer Institute

Background

The incidence of HPV-related oropharyngeal cancer (OPC) is significantly increasing among men, and men with HIV (MWH) are at highest risk. HPV vaccines have been proven effective for the prevention of cervical, vaginal, vulvar, and cancers, but a definitive Phase III trial is needed to assess vaccine efficacy against HPV-OPC. The US-Latin American-Caribbean HIV/HPV-Cancer Prevention Clinical Trials Network (ULACNet) Research on Oral and Cervical Cancer, HPV and HIV in the Americas (*ROCCHHA*) Partnership Center's Trial 201 was designed to evaluate 9vHPV vaccine efficacy for prevention of persistent (≥6 month) oral HPV infection among MWH. The aim of this study is to assess the prevalence of oral HPV prior to vaccination.

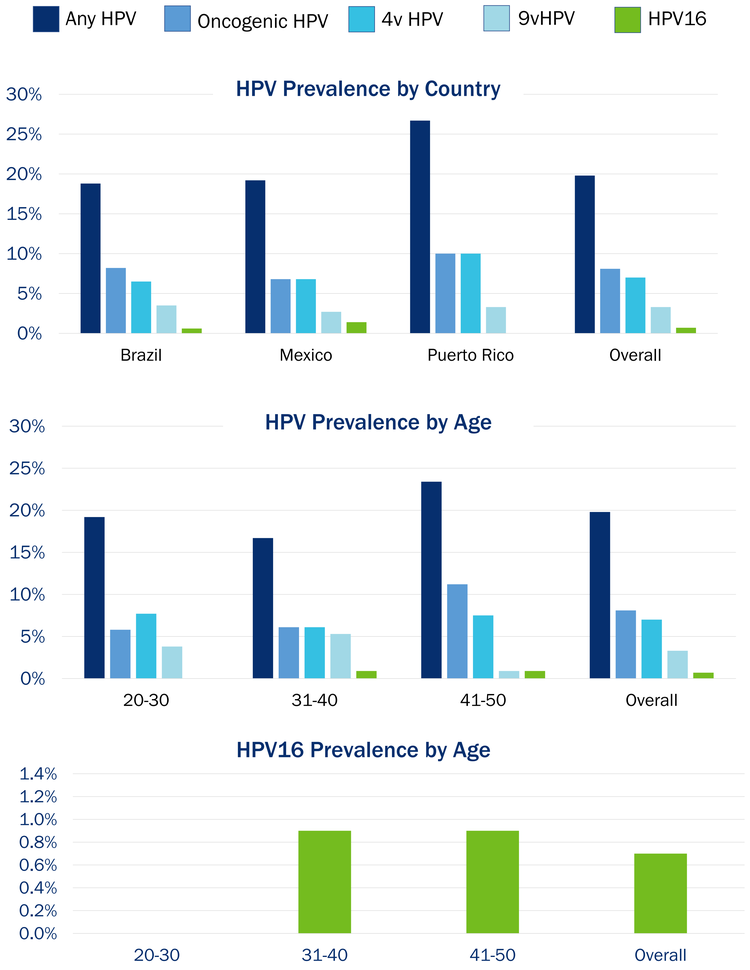
Trial Design

This double-blind, placebo-controlled trial is being conducted in Brazil, Mexico, and Puerto Rico. A total of 500 cisgender men and transgender women with HIV, ages 20-50 years will be randomized 1:1 to receive 9vHPV or placebo on Day 1, Months 2 and 6, with randomization stratified by country and age group. Oral gargle samples are collected day 1, month 7, month 12, and every 6 months thereafter for HPV detection by PCR. Primary analyses will be in the per-protocol populations. Efficacy analysis will occur with accrual of ≥31 endpoint cases.

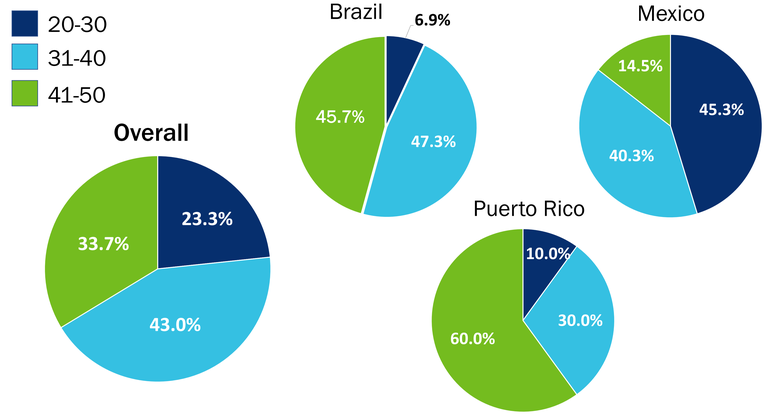
Study Methods

Day 1 oral HPV prevalence among all MWH enrolled was evaluated using the SPF10 PCR-DEIA-LiPA25 system (DDL Diagnostic Laboratory, the Netherlands). HPV genotype distribution was examined for the overall trial cohort and by country and age group (20-30, 31-40, and 41-50 years). Comparisons of men with prevalent HPV infection by country and by age group were tested using Pearson's Chi-squared test. Age at enrollment by country was tested with One-way ANOVA. These analyses were not stratified by recipients of vaccine vs. placebo to retain the study blinding.

HPV Prevalence



Enrollment by Age Group and Site



Results

Trial enrollment began February 2021. As of November 8, 2022, 354 participants were enrolled (175 from Brazil, 149 from Mexico, and 30 from Puerto Rico). Enrollment completion is expected by February 2023. Prevalence of oral HPV was assessed for 273 participants (170 Brazil, 73 Mexico, and 30 Puerto Rico). HPV infection (any type) was detected in 23.1% of participants; 4vHPV types, 9vHPV types, and HPV16 were detected in 3.7%, 8.4%, and 0.7% of participants. HPV types 33 (2.6%) and 35 (1.5%) were the most prevalent oncogenic types. The median age of enrollment was statistically different by country (Brazil, 40; Mexico, 31; and Puerto Rico, 43, $p<0.001$). There were no significant differences in oral HPV type distribution between countries or age groups.

Conclusions

Among MWH, prevalence of oncogenic HPV, particularly HPV16, was low and similar across age groups and countries.