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"Post-market surveillance trial of Gardasil-9 HPV vaccine in adults with HIV**"**

Human papillomavirus (HPV) is estimated to contribute to 5% of cancers globally. Several strains of HPV are considered high risk and have been demonstrated to cause dysplasia and cancers of mucosal epithelial tissues, including the cervix, oropharynx and anus. The Gardasil-4 and Gardasil-9 vaccines, produced by Merck Pharmaceuticals immunize individuals to known oncogenic strains of the virus, including HPV-16 and HPV-18, which are the most prevalent high-risk strains. Patients living with Human Immunodeficiency Virus (HIV) are at greater risk for HPV infection and subsequent dysplasia and neoplasia, making vaccination an important part of preventative care. However, generally, vaccination is less effective in immunodeficient populations and continued surveillance is required for maintenance of optimal vaccine recommendations. This two-armed study seeks to investigate Gardasil-9 immunogenicity and protection in patients living with well-controlled HIV.

The AnoGenital and Oral HPV and Gardasil (AGO-Gard) Trial is a two-arm observational trial with 139 participants enrolled to date. Study participants are recruited through the Infectious Disease clinic at University Medical Center. The first component of the study administered Gardasil-9 to HIV-positive, vaccine-naïve individuals (n=34) with 18-month follow up at 6-month intervals to determine percent seroconversion, serum antibody titers, and HPV infection at each visit. The second part of the study is a cross-sectional investigation of serum antibody titers and mucosal infection rates in Gardasil-4 (n=10) and Gardasil-9 (n=55) vaccine-experienced individuals, with time-since-vaccination documented for each participant to assess durability of HPV antibody titers over time. Serum antibodies will be tested by chemiluminescence immunoassay (Merck) and saliva, anal swabs (men and women), and cervical/vaginal swabs (women) are tested for HPV by PCR followed by high throughput sequencing (HPV-MY-Seq) to determine HPV strains.

Participants in the study are predominantly African-American (77%), male (65%), single (69%) and insured via Medicaid (79%). The average age of participants is 37 years (range, 24-47). All participants are prescribed combination antiretroviral therapy with Biktarvy (bictegravir/emtricitabine/tenofovir) reported most frequently (57%). Fewer than half reported condom use at last sexual encounter. Among vaccine-experienced individuals, 48% tested positive for anal HPV, and among women, 28% tested positive for vaginal HPV. In vaccine-naïve individuals, 67% and 50% tested positive for anal and vaginal HPV, respectively.

HPV vaccination plays a central role in preventing certain types of cancers, and this study provides a multifaceted look at the efficacy of HPV vaccination in a clinically at-risk population. The study will provide insight into the validity of the current vaccine recommendations and a look into HPV strain-specific prevalence in a population living with HIV.