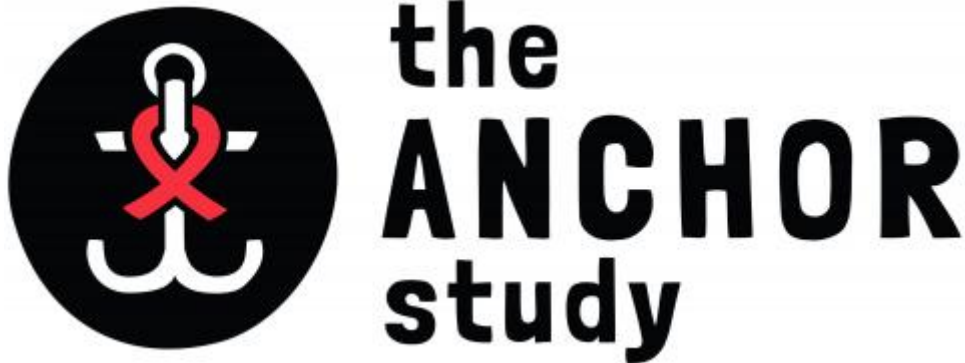


Dr. Joel Palefsky Launches Multi-million Dollar Study Exploring Anal Cancer Treatment

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UCSF Scientist Wins \$89M Grant to Study Anal Cancer In HIV-Infected People

A UC San Francisco investigator has won an eight-year grant from the National Cancer Institute for a major investigation into anal cancer, a debilitating and sometimes fatal disease largely concentrated among people with HIV.

The total amount of the award over the life of the grant is projected to be approximately \$89 million.

Anal cancer disproportionately affects HIV-infected men and women, but the rate of infection is rising among people who do not have HIV and without active intervention, and the number of cases is expected to continue to grow in the general population.

Like cervical cancer and some oral cancers, most cases of anal cancer are associated with human papillomavirus (HPV). Vaccination has been shown to reduce the risk, but the majority of HIV-infected individuals currently at risk for anal cancer are older than age 26, do not qualify for vaccination, and may already have been exposed to the form of HPV known to cause anal cancer.

?Given these strong biological similarities, it is very possible that biomarkers and treatments identified in the study will be applicable to cervical and HPV-associated oral cancer as well,? said Joel Palefsky, MD, a UCSF professor of medicine and principal investigator of the anal cancer project.

The study will focus on determining the effectiveness of treating anal high-grade squamous intraepithelial lesions (HSIL), which are caused by chronic HPV infection, in reducing the incidence of anal cancer in HIV-infected men and women.

Combined with the possibility that anal cancer is preventable, the incidence of anal cancer is

unacceptably high and calls for urgent intervention, Palefsky said.

Compared with the general population, the incidence of anal cancer is increased more than 100-fold among some risk groups of HIV-infected persons, including many who are successfully treated with combination antiretroviral therapy, Palefsky said. There is evidence that anal HSIL is the precursor to invasive anal cancer, which makes it a great target for prevention.

Pioneering Work in Anal Cancer Prevention

Palefsky is founder and president of the International Anal Neoplasia Society, which will hold its inaugural annual meeting Nov. 22- 24 in San Francisco.

Even when anal cancer is not fatal, Palefsky said, there are significant risks of long-term illness and debilitation associated with cancer treatment in those who survive.

The study will enroll 5,058 HIV-infected men and women with anal cancer at 15 sites around the United States. Participants will be randomly assigned to either a treatment arm in which their precancers will be removed to the greatest extent possible or an observation arm in which they will be followed closely without intervention. Participants in both branches of the study will be followed every six months for up to five years, and the incidence of cancer will be determined for both branches.

In addition to investigating whether removing HSIL reduces the likelihood of cancer, the study has three other main research objectives: to determine how HSIL develops into cancer at the molecular level; identify biomarkers to identify those at highest risk of progression to cancer; and identify new treatments for anal HSIL and cancer.

For the first year of the grant, Palefsky will receive \$5.6 million.

We will ramp up from then, with an equal or greater amount going to the project for each year of the study, said Palefsky, who established the UCSF Anal Neoplasia Clinic in 1990 as the world's first clinic devoted to the prevention of anal cancer.

UCSF is a leading university dedicated to promoting health worldwide through advanced biomedical research, graduate-level education in the life sciences and health professions, and excellence in patient care. It includes top-ranked graduate schools of dentistry, medicine, nursing and pharmacy, a graduate division with nationally renowned programs in basic biomedical, translational and population sciences, as well as a preeminent biomedical research enterprise and two top-ranked hospitals, UCSF Medical Center and UCSF Benioff Children's Hospital.

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