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## PRESS RELEASE

## A Randomized Clinical Trial of Infrared Coagulator (IRC) Ablation versus Expectant Management of Intra-Anal High Grade Intraepithelial Neoplasia (HGAIN) in HIV-infected Adults: AMC STUDY # 076

ROCKVILLE, MD (September 20, 2018): Anal high-grade dysplasia (HSIL) ablation may reduce the incidence of invasive cancer, but few data exist on HSIL treatment efficacy and natural regression without treatment. The AIDS Malignancy Consortium (AMC), a National Institute of Health funded group, conducted a prospective, randomized, double arm, open label study to evaluate the complete response rate of intra-anal high-grade squamous intraepithelial lesions treated with Infrared Coagulation (IRC) versus spontaneous regression in HIV-infected people with limited disease. A total of 120 participants were enrolled in the study.

Participants were randomized 1:1 to ablation of anal HSIL with infrared coagulation (treatment group) or no HSIL treatment (active monitoring). Participants were followed every three months with high-resolution anoscopy. Treatment group participants underwent anal biopsies of suspected new or recurrent HSIL. Active monitoring arm participants only underwent biopsies at month 12. The primary endpoint was complete clearance of index HSIL at Month 12.

Complete index HSIL clearance occurred more frequently in the treatment group as compared to the active monitoring group (62% vs. 30%, p<0.001). Having a single index lesion was significantly associated with complete clearance as compared to having 2-3 index lesions. The most common adverse events related to treatment were mild or moderate anal pain and bleeding. No serious adverse events occurred among study participants

Infrared coagulation ablation of anal HSIL results in more clearance of HSIL compared to observation alone. Future studies should identify more effective treatment options so that a greater number of patients can be effectively treated with a single intervention.

**Reference:** 

A randomized clinical trial of infrared coagulation ablation versus active monitoring of intra-anal high-grade dysplasia in HIV-infected adults: An AIDS Malignancy Consortium trial. Goldstone SE, Lensing SY, Stier EA, Darragh T, Lee JY, et al. (Link to abstract)

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http://www.AIDScancer.org