

In 2020, over 29,000 women worldwide were diagnosed with anal cancer. Nearly 90% of cases are associated with chronic infection of human papillomavirus (HPV), which can lead to high grade anal intraepithelial neoplasia (HSIL (AIN)). It is a precancerous lesion that may directly cause anal cancer.

The overall population incidence of anal cancer is 0.7 for women and 0.6 for men per 100,000 people. HIV-positive homosexual men are the group at the highest risk of developing anal cancer (the incidence rate is 77-137 per 100,000). Considering only women, HIV infection is present in only a relatively small percentage of anal cancer patients. In this group 90% of anal cancers are caused by a chronic HPV infection.

The above data shows that, when defining risk groups for anal cancer, the population cannot be narrowed down to HIV-infected, immunosuppressed or homosexual men. It is women with HPV-related gynecological diseases that may be a population particularly vulnerable to AIN and anal cancer. In this situation, the cancer may develop due to chronic HPV infection that has spread from one anatomical region to another. The specificity of the gynecological and anus anatomy makes it more feasible.

Based on the above consideration, patients with HPV-related gynecological diseases may become a potential group where anal HSIL (AIN) screening should be routinely performed in order to reduce anal cancer mortality.

The aim of the study is to determine the overall incidence of anal precancerous disease in patients treated for HPV-related gynecological diseases and to determine the specific risk for each of the HPV-related gynecological cancers and precancers. An additional goal is to determine the sensitivity and specificity of three tests that can be used in a potential screening test for HSIL(AIN) in this group of patients: DNA genotyping of high-risk types of HPV, liquid cytology and Co-test (combination of genotyping test with liquid cytology).

Patients with HPV-related gynecological diseases, e.g. cervical cancer, vulvar cancer or adequate precancerous conditions will be recruited for the study. Each participant will have swab taken from the lower genital tract and from the anal canal. The swabs will be used for cytology and HPV DNA genotyping. The results will be compared to determine whether in the specific patient the HPV infection is present and whether the infection was caused by the same type of HPV virus in both cases. In addition, patients will undergo a specialist examination (anoscopy), that will allow collecting samples of suspicious lesions in order to conduct secondary prevention of anal cancer.

Patients treated for HPV-related gynecological diseases are expected to have a higher than population risk of developing anal precancerous lesion. We also expect that in a particular patient, the same type of virus, that is detected in the lower genital tract, will be responsible for anal infections. The results of the study may in the future imply the extension of indications for screening test for precancerous anal lesions and anal cancer, as well as vaccinations against HPV in the group of patients treated for HPV-related gynecological diseases.