# ANCHOR STUDY

## GRAB sat down with Dr. Gary Bucher

By Mark Nagel

The ANCHOR Study is a longitudinal randomized clinical trial to determine whether treating precancerous anal lesions called high grade squamous intraepithelial lesions (HSIL) is effective in reducing the incidence of anal cancer in HIV positive men and women.

***Mark Nagel:*** If you know you are positive you know to get your viral load and T-cells checked. What else should you be having checked?
***Dr. Gary Bucher:*** In general, all HIV positive men and women should follow the same recommendations that non-HIV infected individual's follow from the US Preventive Services Task Force. HIV positive individuals are at higher risk for some non-AIDS defining cancers. Anal cancer is one of those cancers and the rates are much higher in HIV positive men and women, especially in HIV positive men who have sex with men. The ANCHOR Study will help determine whether screening HIV positive men and women and treating HSIL will prevent anal cancer. If the ANCHOR Study shows that the incidence of anal cancer is reduced, then there is a high probability that screening and treatment to prevent anal cancer will added to standard of care clinical guidelines for individuals with HIV. Currently, screening for HSIL in HIV positive men and women is not standard of care though many believe it should be.

***M.N:*** Why is this study so important?
***G.B:*** The ANCHOR Study is so important because the incidence of anal cancer continues to rise. Overall, it is estimated that the proportion of individuals with anal cancer who are also infected with HIV increased from 1980-1984 to 2001-2005, rising from 1.1% to 28.4% among males, and from 0% to 1.2% among females. Recent studies indicate an incidence of 131/100,000 among HIV-infected MSM in the US. This study is also important because there are no preventative guidelines in place for anal cancer. This study will provide the evidence required to add anal cancer prevention to preventative cancer guidelines across the nation.

***M.N:*** If you are positive and already have a doctor, why should you participate in this study?
***G.B:*** Most HIV positive men and women do not even know they are at higher risk for anal cancer. They should participate in the study to once again be at the forefront in HIV care to help us determine whether all HIV positive individuals should be screened and treated for HSIL to prevent anal cancer. Most patients do not want to have an anal exam and most doctors do not want to perform an anal exam, so it is a great way to get the anal care HIV patients need and deserve in a professional and respectful atmosphere while at the same time getting screened for anal cancer.

***M.N:*** Should you still talk this over with your doctor?
***G.B:*** Of course you should discuss this with your own doctor. The staff at the Anal Dysplasia Clinic Midwest is also available to discuss this with you.

***M.N:*** Are there any risks involved with this study?
***G.B:*** The point of doing a randomized clinical trial is to compare two groups. In the ANCHOR Study, participants will be screened for HSIL. If HSIL is found, and they qualify for the study, they will be randomized to active monitoring or treatment of HSIL. Remember, the primary goal of the study is to determine whether treating HSIL is effective in reducing the incidence of anal cancer. There is a risk of developing anal cancer in the active monitoring arm but also in the treatment arm. Participants will be followed closely so if cancer develops it will be found very early and more easily treated.

***M.N***: How long is this study?
***G.B:*** Each participant will be followed for at least 5 years. We are hoping to reach full enrollment of 5,058 participants in the first 3 years so total study time will be 8 years.

***M.N:*** Do you get paid to participate?
***G.B:*** Participants are at least every 6 months and are given $100 at the end of each visit.

***M.N:*** Will there be any pain?
***G.B:*** There may be some discomfort during the procedure called High Resolution Anosocpy (HRA). Mostly, people feel pressure during the exam. There may be some discomfort with minor pain and irritation with the treatments used for HSIL but nothing that can't be controlled with over the counter medications or mild pain medications.

***M.N:*** What is expected of you during this study?
***G.B***: Participants are expected to make it to their study appointments and to adhere to any treatment recommendations.

***M.N:*** Most importantly, can you still have sex if you participate?
***G.B:*** Of course participants can still have sex while being in the study.

***M.N:*** What if I change my mind?
***G.B:*** Participants can always change their mind without fear of any repercussions. Of course, we would hope everyone will continue in the study for the full five years but circumstances could change.

***M.N:*** So how is HSIL treated?
***G.B:*** If the participant is randomized to the treatment arm, the doctor and participant will decide what is the best treatment for that particular individual. Treatments basically fall into two categories: topical treatments and localized lesion destruction. The two topical treatments are fluorouracil cream or imiquimod cream. Both have advantages and disadvantages and they would be discussed with the participant to see which cream would be best for particular participants HSIL. The three localized lesion destruction treatments are electrocautery(EC), laser, or infrared coagulation (IRC). Usually the destruction method used is determined by which method the provider is comfortable with using. They all accomplish the same thing.

***M.N:*** What are the side effects of treatment?
***G.B***: The creams can cause discomfort, burning, itching, bleeding or irritation. The destruction treatments can cause mild discomfort and possibly some bleeding.

***M.N:*** Why compare treatment to monitoring?
***G.B:*** We need to see whether treating HSIL lesions prevent anal cancer. To accomplish that, we need to have an equally matched group where one group gets treatment and the other group does not. We can then see whether there is less anal cancer in the treatment arm versus the monitoring arm.

***M.N:*** What are the advantages of being in either arm of the study?
***G.B:*** The biggest advantage is that everyone will be screened and followed for anal cancer where they probably would not have been screened or monitored without being in the study.

***M.N:*** How does someone participate in the study?
***G.B:*** Interested individuals can call the Anal Dysplasia Clinic Midwest at 312-623-2625 to speak to someone to see if they qualify for the study. If they qualify for the study, a screening appointment will be made and we will screen them for the study.

***M.N:*** Best way for our readers to find out more information of your study?
***G.B:*** They can go the website **www.ANCHORStudy.org** or call the Anal Dysplasia Clinic Midwest at **312-623-2625** to discuss the study in detail with one of the staff.