CWRU/UH AIDS Clinical Trials Research Site
ACTG5355: A clinical trial to evaluate the safety and immune response to an anti-cytomegalovirus (CMV) vaccine in adults living with both HIV and CMV
Potential Participant Summary

Brief Background and Purpose of this Study: Since the early days of the HIV epidemic, cytomegalovirus (CMV) was the cause of common and devastating opportunistic infections experienced by people with HIV. CMV is a very common virus that usually causes few, mild, or no symptoms and typically remains in the body for life. However, in people with weakened immune systems, such as people with untreated HIV infection, CMV can cause very serious symptoms.

These symptoms are much less common now as people living with HIV can maintain a healthier immune system by taking anti-HIV medicines and controlling HIV viral loads. However, we know that CMV infection, even in people with controlled HIV, places a large ongoing burden on the immune system. This burden results in ongoing immune activation and inflammation, both contributors to illness and disease.

This trial is looking at the safety and immune response of an investigational anti-CMV vaccine, MVA Vaccine Encoding CMV antigens (Triplex®) in people living with HIV and CMV. The trial is also looking to see if the vaccine decreases immune activation and inflammation. This will be the first time that this type of information will be collected. The vaccine has not been approved by the FDA and can only be given to people in clinical research trials.

The current standard of care for individuals with both HIV and CMV includes effective treatment for HIV but does not include treatment of CMV with either medication or vaccination – unless there is evidence that the CMV is causing or contributing to illness.

Inclusion Criteria (things that must be true to join the trial):
- Living with HIV and with CMV and between 18 and 65 years old.
- On anti-HIV medications that are controlling your HIV for at least the past year.
- Agree to use birth control methods if capable of becoming pregnant or impregnating someone else.

Exclusion Criteria (things that cannot be true in order to join the trial):
- History of CMV disease/symptoms within past 12 months or use of anti-CMV drugs in the past 2 weeks.
- Currently have hepatitis B or hepatitis C.
- Currently have a sexually transmitted infection, such as, gonorrhea, syphilis, or chlamydia.
- Receipt of any vaccine (including for COVID-19) within the previous 4 weeks.
- Recent serious illness or condition requiring hospitalization.
- Breastfeeding or pregnant.

Participants can talk with the study staff about the complete list of inclusion/exclusion criteria.

What happens in the trial:
In this trial, participants are randomly (like the flip of a coin) placed in one of two study groups, the vaccine group and the placebo group. People placed in the vaccine group will receive the Triplex study vaccine. People in the placebo group will receive a placebo injection, a saline solution. Participants will not know which group they are in until the study is over. Participants have a 2:1 chance of receiving the vaccine: 60 will receive the vaccine and 30 will receive placebo.

Participants will receive injections into the muscle of their shoulder 2 times: once at study entry and again about 4 weeks later. Participants must continue to take their anti-HIV drugs throughout the study.

Participants will be on the study for about 2 years. In the first month of the study, there are 2 study visits and 2 phone contacts with clinic staff. After that, there are 5 more visits over the next 16 months.

Blood and urine samples will be collected at scheduled clinic visits for safety evaluations and other research testing. Participants will complete questionnaires on adherence to ART and use of other drugs. For the first 5 days after each injection, participants will record their temperature and for 4 weeks following each injection will complete a daily study diary. At several of the clinic visits, saliva, rectal swabs, and/or genital fluid (semen or vaginal swab) will be collected.
Compensation provided.

For more information on this study please contact us at:
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