Alabama Vaccine Research Clinic

Clinical Research Trials Guide: Vaccines & Microbicides

University of Alabama at Birmingham
Introduction | About the AVRC

Since 1994, the Alabama Vaccine Research Clinic (AVRC) at the University of Alabama at Birmingham (UAB) has been dedicated to working within the Birmingham and surrounding communities to provide education on the prevention of various infectious diseases, preventative and therapeutic vaccines, as well as opportunities for our community to help end infectious diseases by volunteering to participate in clinical research trials.

We know that vaccines are one of the most effective means to prevent illness yet, for many diseases, no vaccines exist or are minimally effective. Our Mission is to help develop new vaccines that can prevent a number of diseases for which treatment is not available or is suboptimal. The AVRC is committed to assisting in the research and development of vaccines that will protect against afflictions such as HIV/AIDS, Genital Herpes, Influenza, Malaria, Smallpox, Tuberculosis and more.

The AVRC is housed by the UAB School of Medicine and is funded by the National Institutes of Health (NIH). This clinic is also Alabama’s only site for the HIV Vaccine Trials Network (HVTN)—an international effort to find and test and effective HIV prevention vaccine that will work safely and effectively in diverse populations worldwide. Other organizations hosted locally by the AVRC include the AIDS Clinical Trial Group (ACTG), HIV Prevention Trials Network (HPTN), and the Microbicide Trials Network (MTN).
What is a Vaccine?

A vaccine is a drug or product that serves as a catalyst to stimulate the recipient’s immune system in order to produce resistance or immunity to a certain disease, in turn, protecting the person from acquiring the disease. Most people are familiar with injectable vaccinations that are administered via a needle; however, oral vaccines and topical vaccines that are sprayed into the nose are also available.

What is a Microbicide?

Microbicides, currently in development, are creams, gels, suppositories or films that eliminate or act as a barrier to prevent pathogens from infecting healthy cells. At present, researchers are studying how microbicides may be able to prevent HIV—both before and after infection—and believe that this may be a good choice for HIV prevention in women.
What is a Clinical Research Trial?

Clinical research trials investigate new ways to prevent, detect, or treat disease. Preventing, detecting or treating diseases may involve creating new drugs, using a new combination of drugs, finding new ways to use existing treatments and discovering new surgical procedures or devices. The purpose of conducting clinical trials is to find out if a new test, procedure, or treatment is safe and works effectively.

Clinical Trial Phases

Clinical research trials are conducted in phases or levels in order to preserve safety and answer different questions. There are four (4) phases:

Phase I: An experimental drug or treatment is tested in a small group of people for the first time. The purpose is to evaluate safety and identify side effects.

Phase II: The drug or treatment is given to a slightly larger group of people to further evaluate its safety and to determine its effectiveness.

Phase III: The drug or treatment is given to large groups of people to confirm its safety and effectiveness, monitor side effects, and compare it with existing treatments.

Phase IV: Drugs or treatments in this phase have been FDA approved and made available to the public. Researchers continue to track safety, risks, benefits, and optimal use.
Volunteers | Clinical Trial Participants

Finding new drugs, treatments, or procedures that are both safe and effective would not be possible without the help of people who volunteer to participate in clinical research trials. A common misconception about clinical research trials is that only “sick” people can participate but, contrary to this belief, volunteers are representatives of an entire population so people of various genders, backgrounds, race/ethnicities, ages, and health statuses are desired.

People volunteer to be in clinical research trials for various reasons. Some people know someone who is affected by an illness or disease and want to help them by contributing to medical research; some are philanthropic; some are just interested in research, and some may wish to gain access to treatments or drugs before they become widely available.

Although different clinical trials have different guidelines about who can participate, all volunteers play an important part in clinical research!
Volunteers | Community Advisory Board

For those who are interested in learning more about vaccines and vaccine research or helping to prevent illnesses in other ways, the Alabama Vaccine Research Clinic also hosts a Community Advisory Board or CAB for short.

A CAB consists of people from various communities, age groups, ethnicities, disciplines, et cetera, who act as representatives for others in their respective groups and communities. These individuals then meet with representatives of an institution to exchange information and ideas between both parties. The idea is to utilize this partnership to bridge the information gap between researchers and the communities they serve while simultaneously strengthening the capacity to respond to critical research needs in the future. This arrangement allows all perspectives to be heard and seeks to foster mutual understanding, trust, and collaboration in preventing infectious illnesses.
# Ongoing/Upcoming Vaccine & Microbicide Clinical Research Trials

<table>
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<tr>
<th>Study</th>
<th>Purpose/Investigating</th>
<th>Eligibility Criteria</th>
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<tr>
<td>Flu Vaccine Study</td>
<td>Phase II: Study assessing safety, reactogenicity, and immunogenicity of a Sanofi Pasteur A/H7N9 inactivated Influenza vaccine administered intramuscularly with or without AS03 adjuvant</td>
<td>All adults aged 18 or older, HIV negative, Hepatitis B/C negative, In good health</td>
<td>Santorra King 205-996-4099 Pamela Cunningham, RN, MPH</td>
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<td>[Upcoming]</td>
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<td>HPTN 083 [IMPROVE]</td>
<td>Phase IIb/III: Study of injectable Cabotegravir compared to daily oral Tenofovir Disoproxil Fumarate/Emtricitabine (TDF/FTC), for pre-exposure prophylaxis (PrEP)</td>
<td>Age 18 or older, Men and transgender women (Male to Female) who have sex with men, HIV negative, In good general health</td>
<td>Andy Yousef 205-934-6777 Santorra King 205-996-4099 Heather Charlton, RN</td>
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<td>HVTN 108</td>
<td>Phase I/IIa: Evaluating the safety and immunogenicity of HIV clade C DNA, and of MF59 or AS01b-adjuvanted clade C Env protein in various combinations</td>
<td>Age 18-40, HIV negative, In good general health</td>
<td>Santorra King 205-996-4099 Aeryn Peck, RN, MSN</td>
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<td>HVTN 115 Anticipated Start October 2017</td>
<td>Phase I: Study to evaluate the safety and immunogenicity of EnvSeq-1 Envs adjuvanted with GLA-SE, administered alone or with DNA Mosaic-Tre env, in healthy, HIV-uninfected adults</td>
<td>Age 18-50, HIV negative, In good general health</td>
<td>Santorra King 205-996-4099 Pamela Cunningham, RN, MPH</td>
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<td>Study</td>
<td>Phase/Design</td>
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<td>Contact Information</td>
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| **HVTN 118**    | **[Janssen Ascent]** Phase I/IIa: Assessing safety/tolerability and immunogenicity of 2 different prime/boost regimens: priming with tetravalent Ad26.Mos4.HIV and boosting with tetravalent Ad26.Mos4HIV and either Clade C gp140 plus adjuvant OR a combination of Mosaic and Clade C gp140 plus adjuvant | • Age 18-50  
• HIV negative  
• In general good health | Santorra King 205-996-4099  
Pamela Cunningham, RN, MPH |
| **HVTN 704/HPTN 085** | **[AMP Study]** Phase IIb: Evaluating the safety and efficacy of VRC01, a broadly neutralizing monoclonal antibody in reducing acquisition of HIV-1 infection | • Age 18-50  
• Men who have sex with other men or transgender (M-F or F-M)  
• Must have had anal intercourse with 2 or more male or transgender partners in past 6 months OR condomless anal intercourse with 1 male or transgender partner in the past 6 months | Andy Yousef 205-934-6777  
Santorra King 205-996-4099  
Catrena Johnson, RN, MSN  
Heather Logan, RN, DNP |
| **MiTox**       | Controls Needed: Investigating the role of HIV-infection and antiretroviral therapy related mitochondrial toxicity in accelerated aging | • HIV negative between the ages of 55-65 OR  
• PrEP users aged 20 or older Must have been using PrEP for at least 3 months | Pamela Cunningham, RN, MPH  
205-975-2841  
Sonya Heath, MD |
| **MTN 029**     | Enrollment Closed Phase I: Investigating vaginal rings in lactating women | • Age 18 or older  
• At least 6 weeks postpartum  
• HIV negative | Faye Heard 205-996-4405 |
| **MTN 030**     | Enrollment Closed Phase I: Investigating safety and pharmacokinetics of combination microbicide/hormonal birth control ring | • HIV negative females ages 18 to 45  
• Must have regular menstrual cycle | Faye Heard 205-996-4405 |
<p>| <strong>MTN 035</strong>     | Phase IIa: Assessing acceptability, tolerability, and adherence of two | • Men who have sex with men and transgender women | Faye Heard 205-996-4405 |</p>
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| In Development | dapivirine gel placebo products applied rectally | • Ages TBD  
• HIV negative | |
| MTN 036 | Upcoming | Phase I: Assessing PK and safety of three extended duration DPV vaginal ring formulations when used continuously for 90 days vs. replaced monthly | • HIV negative females  
• ages 18 to 45  
• Not pregnant or planning to become pregnant during participation in study |
| Faye Heard 205-996-4405 | |
| MTN 039 | In Development | Phase I: Safety and PK Study of TDF and EVG Administered Rectally | |
| Faye Heard 205-996-4405 | |
| Pneumococcal Vaccine Immune Responses | [PVIR] Enrollment Closed | Concept: Investigating immune responses to clinically approved vaccines designed to protect against pneumococcus infections (Prevnar and Pneumovax) | • HIV negative men and women  
• Aged 65 or older  
• Have NOT previously received Prevnar or Pneumovax vaccines |
| Santorra King 205-996-4099  
Pamela Cunningham, RN, MPH  
Paul Goepfert, MD | |
| ACTG A5332 | [Reprieve] | Randomized trial to prevent vascular events in HIV | • HIV positive  
• Age 40-75  
• Have been on antiretroviral therapy (ART) for at least 6 months  
• No history of heart disease or cancer in last 3 years |
| Santorra King 205-996-4099  
Aeryn Peck, RN, MSN  
Olivia Hogue, RN | |
| Vical 2 | Enrollment Closed | Phase II: Evaluating the safety and efficacy of herpes simplex virus, type 2 (HSV-2) therapeutic DNA vaccine in adults with symptomatic genital HSV-2 infection | • Age 18-50  
• HIV negative  
• A minimum of 1 year history of recurrent genital herpes |
| Santorra King 205-996-4099  
Aeryn Peck, RN, MSN  
Nick Van Wagoner, MD | |
Resources

Alabama Vaccine Research Clinic
University of Alabama at Birmingham
908 20th Street South | CCB 310
(205) 975-2839 | www.uab.edu/avrc

AIDS Clinical Trial Group (ACTG)
www.actgnetwork.org

AIDS Vaccine Advocacy Coalition (AVAC)
www.avac.org

AMP Study
www.ampstudy.org

Centers for Disease Control and Prevention (CDC)
www.cdc.gov

Clinical Trials
www.clinicaltrials.gov

HIV Prevention Trials Network (HPTN)
www.hptn.org

HIV Vaccine Trials Network (HVTN)
www.hvtn.org

Microbicide Trials Network (MTN)
www.mtnstopshiv.org

National Institutes of Health (NIH)
www.nih.gov

Research Match
www.researchmatch.org