

ACTG HIV RESERVOIRS COHORT (AHRC) UPDATES



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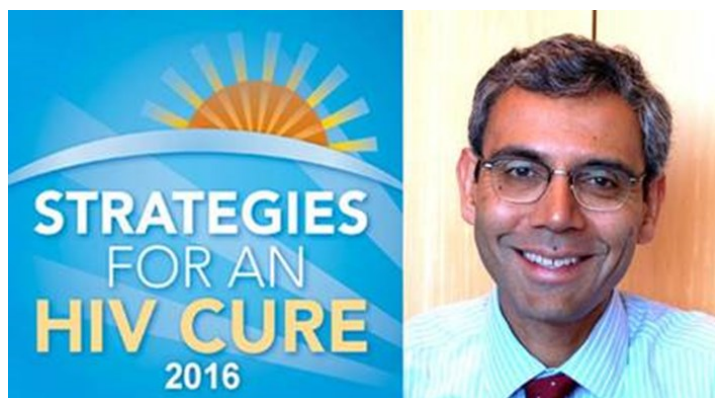
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A5321/A5341s DISCUSSED AT STRATEGIES FOR AN HIV CURE MEETING

The 3rd Strategies for an HIV Cure Meeting was held in November 2016 at the National Institutes of Health (NIH) in Bethesda, Maryland. Dr. Raj Gandhi, one of the chairs of A5321, gave a presentation about A5321 and A5341s.

The main purpose of this meeting is to increase face-to-face discussion and encourage researcher from different places to work together. Researchers from universities, non-profit organizations, industry, and members of the community attended this meeting. Representatives of the AIDS Clinical Trials Group (ACTG) and the Martin Delaney Collaboratories were speakers, along with other researchers and members of the community.

Dr. Gandhi highlighted some of the goals of



Raj Gandhi, MD, A5321 Protocol Chair

A5321 and A5341s, two long-term studies designed to help understand more about HIV reservoirs. Reservoirs are places in the body that HIV hides in when viral load is suppressed in the blood.

Dr. Gandhi emphasized the value that study participants bring to the study—not just by contributing blood and tissue samples—but by their dedication over time.

The participants have been studied over several years. The data and specimens from the study provide an opportunity for other researchers to work with the team leading the study to perform new, specialized tests on the blood and tissues provided by the participants. Results from the coded specimens can be linked to other coded information already collected.

See page 2

Study Titles

A5321: ACTG HIV Reservoir Cohort Study

A5341s: Size and Decay of HIV-1 Reservoirs in Tissues and Spinal Fluid

AHRC BY THE NUMBERS

A5321 (Main Study)

- 353 enrollees
- 61 women & 292 men
- 73 Hispanics/Latinos
- 34 different ACTG sites
- 80 spinal taps to date

A5321 (Main Study)

- Group 1: 321 (91%)
- Group 2: 22 (6%)
- Group 3: 10 (3%)

A5341s (Substudy)

- Enrollees 34

A5341s Substudy Cohorts

- A Spinal Tap: 20
- B Leukapheresis: 19
- C Gut Biopsy: 3
- D Genital Secretions 22

A5321/A5341s DISCUSSED AT STRATEGIES FOR AN HIV CURE MEETING (FROM PAGE 1)

The data showed that inflammation before taking HIV medicine was related to inflammation and levels of HIV years later.

Dr. Gandhi reported on the levels of inflammation in the blood of participants. Inflammation is the body's reaction to tissue damage or foreign substances. Inflammation results in certain immune cells getting activated or producing chemical messages.

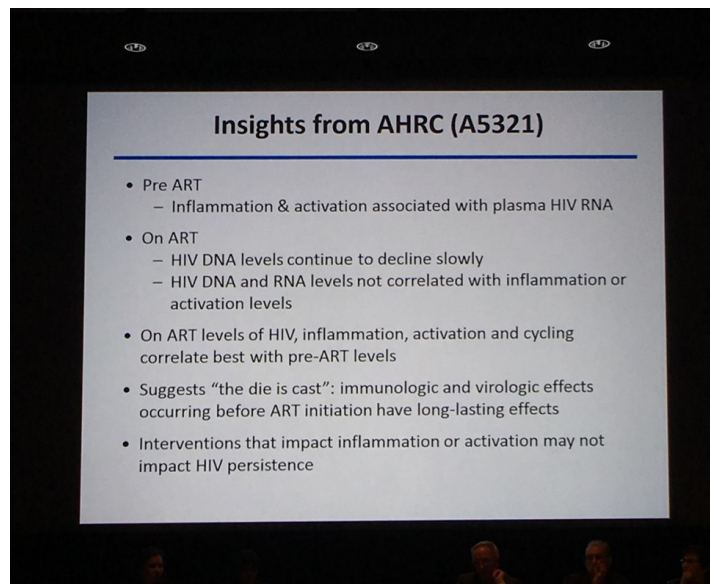
Inflammation can be measured in some white blood cells of the immune system and in plasma (liquid part of the blood). Dr. Gandhi described levels of inflammation present before participants began to take treatment for HIV. He also described levels of inflammation several times after participants had been taking HIV treatment for years.

The data showed that inflammation before tak-

ing HIV medicine was related to inflammation and levels of HIV years later.

These results have been submitted to a medical journal. We hope that they will be published

soon (this year). After the results have been published, we will share more details and other results from the study. Look forward to more information in a future newsletter!



One of the slides from the presentation

Q AND A: LEUKAPHERESIS

Q1: What is a leukapheresis?

A1: This is a procedure where your white blood cells are separated from other parts of your blood. For this study, the white blood cells are used for research. The rest of the blood is returned to the participant.

Q2: How long does it take?

A2: It takes about 2-4 hours.

Q3: Does it hurt?

A3: It is uncomfortable:

- when a needle is placed into each arm and
- because you are supposed to sit with your arms still for the entire procedure.

Q4: What should I wear?

A4: Wear loose sleeves so you can roll them up above your elbows.

Q5: Is there a “prep”?

A5: There is no specific prep. It is a good idea to drink lots of non-alcohol fluids for 3 days before a leukapheresis. Avoid aspirin and non-steroidal drugs (like ibuprofen) for 5 days before.

Q6: What can I do afterwards?

A6: You can go home or to work afterwards. You should avoid heavy lifting for a few days.

For this study, the white blood cells are used for research. The rest of the blood is returned to the participant.

SITES REGISTERED FOR A5321&A5341s

Current ACTG Sites registered for A5321 and A5341s



29 current U.S. sites are registered to conduct A5321 and the majority are also registered to conduct the tissue substudy A5341s

DEMYSTIFYING FLEXIBLE SIGMOIDOSCOPY AND BIOPSIES FOR A5341s

Biopsy means collection of tissue.

Purpose:

- * To collect a small amount of tissue from the inside (lining) of the gut
- * To see how the virus persists in people on HIV treatment
- * To look at how the immune system in the gut and the virus interact

General Info:

- * A flexible sigmoidoscopy ("flex sig") is a common outpatient procedure
- * Flex sigs are done by a gut specialist doctor (gastroenterologist)
- * A flex sig is simpler and easier than a colonoscopy

- * The instrument used is a very skinny, flexible tube with special "tweezers" on the end
- * A flex sig with biopsies takes about 20 minutes, not including check-in

Preparation

- * The preparation needed before a flex sig is 1 or 2 plain or salt water enemas
- * Unless someone has severe anxiety, sedation is not needed for a flex sig

Procedure

- * Most people have a feeling of abdomen (belly) fullness during a flex sig.

- * Each biopsy (piece of tissue) is about 1/3rd the length of a grain of rice (about 3-4mm or 1/10th of an inch)
- * Gut biopsies don't hurt because gut tissue doesn't have pain receptors
- * Multiple biopsies will be collected

Post-procedure

- * Participants will be able to return home or go to work
- * They still may have a feeling of belly fullness & some gas
- * There will be some blood in the stool for a few days

Each biopsy (piece of tissue) is about 1/3rd the length of a grain of rice (about 3-4mm or 1/10th of an inch.)

Your site Info

Primary Business Address
Address Line 2
Address Line 3
Address Line 4

Phone: 555-555-5555
Fax: 555-555-5555
E-mail: someone@example.com

The mission of the ACTG Network is to reduce the burden of disease due to HIV, tuberculosis, and viral hepatitis.



actgnetwork.org

One thing that they want to communicate is a big "THANK YOU!" to all participants in research studies.

ACTG HIV Reservoirs Cohort study (AHRC, A5321) is a long-term study, designed to assess patterns of reservoir decay, including what factors determine both the size of HIV reservoir and its decay in people living with HIV on long-term ART



- Substantially larger than previous studies
- Samples stored over time available from participants who have received ART for much longer than in previous studies
- Greater ability to assess whether participants on long-term ART have different reservoir decay patterns (e.g. a subset with continuous decay) and to identify factors associated with reservoir decay

SITE HIGHLIGHTS: UNIVERSITY OF NORTH CAROLINA (UNC) THERAPEUTIC Apheresis UNIT

Sites enrolling in A5341s Cohort B collaborate with local organizations that perform leukapheresis. (See page 2 for Q & A about leukapheresis). The University of North Carolina at Chapel Hill (UNC)'s ACTU Site Coordinator, Susan Pedersen, recently interviewed the staff of their collaborating apheresis unit.

The unit is called the UNC Therapeutic Apheresis Unit. It has been doing apheresis for research studies for over 20 years. It has 7 RNs (nurses) on its staff.

Apheresis is a procedure to remove some part of the blood and return the rest back to the donor. At this unit, they are able to collect different parts of the blood for different research projects. In addition to white blood cell collection for A5341s and other studies, they can also collect plasma,

stem cells and do red blood cell exchanges.

Besides collecting blood, they also do specialized treatments using a specific type of machines. They do a procedure called photopheresis (light treatment for blood cells) for graft-versus-host disease treatment. They also have the only machine in the state of North Carolina that can do "Liposorber" treatment for extremely high (familial) cholesterol.

In 2016, 60 different participants in research studies conducted by UNC ACTU CRS investigator, Dr. David Margo-



Four of the UNC Therapeutic Apheresis Unit's nurses

lis, had apheresis. The unit's nurses are happy to know that if there is a research "breakthrough", they were part of the process. One thing that they want to communicate is a big "THANK YOU!" to all participants in research studies. They emphasized that clinical research doesn't move forward without participants.