Fall 2020

Adolescent HIV Research Consent Index (AHRCI) Supporting Materials

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The study in the video you just watched, and the consent form you'll read next, isn't real. We're not ACTUALLY asking you to join the study in the video.

You should read the consent form carefully. After each page you'll be asked 1-3 questions about what you just read. You won't be able to go back to view the information you just read. If you click the back or refresh button in your internet browser you might get locked out of the survey.

When reading though the info and answering the questions, we'd like you to pretend that you've had anal sex without condoms before, if you haven't already. This is because we'd like you to put yourself in the shoes of someone who might be asked to be in a study like the one you'll read about.

The more questions you answer correctly in this section of the survey, the higher your score will be, and the greater your chances will be for getting a bonus $30 online Amazon gift card. So, we encourage you to try your best!

Title of Research Study: A Phase 2a Crossover Trial Evaluating the Safety of and Adherence to Oral Truvada and Injectable Cabotegravir in HIV-Uninfected Cisgender Adolescent Men and Transgender Women Who Have Sex with Men

Investigator: Dr. Skylar Anderson, Midwest Research College

Introduction

This research study is funded by the National Institutes of Health (NIH), which is a part of the United States (US) government. Before you decide if you want to join this study, please read this form, which will give you information about this study.

The purpose of this study is to test two drugs that may help prevent teenagers from getting HIV. One drug is a pill called Truvada. The other drug called cabotegravir (CAB) comes in pill and injection (shot) form. The CAB shot and Truvada pill both work by stopping HIV from making copies of itself inside the body.

Why am I being asked to take part in this research study?

You are being asked to take part in this research study because you are between ages 14 and 19, a cisgender man (your birth sex and gender identity are male) or transgender woman (your birth sex is male and gender identity is female), and **have had unprotected (condomless) anal sex with male partners** which may put you at risk for HIV.

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Please answer the following about the IMAGINARY study in your own words.

1. Name 1 personal characteristic and 1 behavior that are the reasons why you are being asked to participate in this study.

What is the purpose of this study? Why is this research being done?

The Truvada pill and the CAB shot are safe and effective ways to prevent HIV in adults. In order for the drugs to be effective enough to prevent HIV, the pill has to be taken every day and people have to get a new shot every 2 months. The US Food and Drug Administration (FDA) approved both drugs for HIV prevention in adults, but not for teenagers.

This study is being done for two main reasons:

1) To find out how **safe** the shot and pill are for teenagers. What we mean by "safe" is making sure the side effects of the shot and pills are not worse than the side effects in adults.

2) To find out how well teenagers can **adhere** to taking the pill and shot. The pills and shots only work if they are taken the way they are supposed to be taken. So, what we mean by "adherence" is looking at teenagers' ability and desire to go to a doctor's office to get the shot every 2 months and/or take the pills every day in order for the drug to work well enough to prevent HIV.

So far, studies have shown the shot and pill were as safe for teenagers as adults, but the number of teenagers studied has been very small. Also, a few studies showed the drugs might not be as effective for teenagers because some did not take the pills every day or get the shot every two months, which placed them at risk for getting HIV. The FDA asked for more studies with larger groups of teenagers to learn more about the safety and effectiveness of the drugs for teenagers.

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Please answer the following question in your own words.

2. How often do people need to get the CAB shot AND how often do they need to take the Truvada pill in order to protect themselves against HIV?

3. What is the purpose of this study? That is, what two main things are scientists trying to find out by conducting this research?

If you agree to be in the study, we will do two types of tests to make sure the study is safe for you.

First, you will take an **HIV test**. We will tell you your test results when they come back (up to 10 days later). You will not be able to join the study if the test shows you have HIV, because the study drugs might interfere with the drugs to treat HIV, but we will refer you to a doctor for treatment.

Second, if you don't have HIV, we will test whether the CAB medication is safe for you by asking you to **take pills containing the same drug (CAB) as the shot once a day for 5 weeks** to make sure you will not have a serious side effect to the drug in the shot. "Serious" means you have more than one abnormal test result or severe nausea, diarrhea, or vomiting that doesn't get better within a week.

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Please answer the following about the IMAGINARY study in your own words.

4. What are the 2 types of tests we will do to make sure the study is safe for you?

What happens in the next part of the study?

If you don't have HIV or a serious side effect to the CAB pill you will be asked to join the next part of the study. You will take drugs in 3 different 6 month phases.

You will be assigned to either Group A or Group B.

- Group A: If you are assigned to this group you take the Truvada pills for the first 6 months, then the CAB shot for 6 months, then during the last 6 months you decide whether to take the pill or shot.
- Group B: If you are assigned to this group you get the CAB shot for the first 6 months, then the Truvada pills for 6 months, then during the last 6 months you decide whether to take the pill or shot.

	First 6 months	Second 6 months	Third 6 months
Group A	Take pills every day	Get shot every 2 months	Your choice: shot (every 2 months) or pill (every day)
Group B	Get shot every 2 months	Take pills every day	Your choice: shot (every 2 months) or pill (every day)

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Please answer the following about the IMAGINARY study in your own words.

5. You just read about 3 different phases of the study each lasting for 6 months. What are the 3 phases?

6. Thinking ahead, do you think you would choose the pill or the shot during the last 6 months of the study?
   - ❍ I would definitely choose the PILL condition in the last 6 months
   - ❍ I would probably choose the PILL condition in the last 6 months
   - ❍ I would definitely choose the SHOT condition in the last 6 months
   - ❍ I would probably choose the SHOT condition in the last 6 months
   - ❍ *I do not want to answer*

7. Please explain why you would choose the pill or shot condition in the last 6 months by comparing how the risks or benefits of the 2 different conditions would affect you.

Again, put yourself in the shoes of someone who might be asked to be in this study, by imagining you've had anal sex without a condom (if you haven't already).

How will I be assigned to Group A or Group B?

You will be randomly assigned into group A or B. This means that which of the two drugs you will use in the first 6 months of the study will be decided by chance. Random assignment is like a coin toss, so everyone has the same 50/50 chance of being in Group A or B. Neither you nor the study staff can decide which group you will be in. Random assignment is used so that scientists can make sure the order in which you take the drugs does not influence how well each drug works.

What are my responsibilities if I participate in the study?

As a participant you have 3 important responsibilities:

1) **Take the study drugs the way you are supposed to.** This means that you take the pills every day and get the shot every two months. You might not be protected against HIV during the study if you don't take the pills or shot the way you are supposed to.

2) **Use a condom when you are having sex.** The Truvada pill and CAB shot work best to protect you against HIV if you use a condom during sex. It is also important to still use a condom when you are having sex because neither the CAB shot nor the pill protects you from getting other sexually transmitted infections like chlamydia, gonorrhea, or herpes.

3) **Visit the clinic for up to 13 checkups.** For each phase of the study, you will have a check-up 1 week after you start using any drug. You will then visit the clinic every 2 months when you are getting the CAB shot and visit the clinic every 3 months when you are taking the Truvada pills.

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Please answer the following about the IMAGINARY study in your own words.

8. What are your 3 important responsibilities if you are in the study?

Each visit will take about 2 hours to complete.

In addition to giving you the pills or shots at visits, you will fill out surveys about your sexual activity and receive free sexual health counseling, condoms, and lubricant.

Medical staff may also conduct the following medical procedures:

- Give you a physical exam to make sure you are healthy.
- Draw blood to test you for HIV, to check the levels of drug in your blood, and to make sure you are healthy. They will also give you the results of any blood tests.
- Do urine samples and rectal swabs to test for STIs.
- Treat STIs and refer you to other services, if you need them.

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Please answer the following about the IMAGINARY study in your own words.

9. List at least three medical procedures medical staff may conduct when you visit the clinic, not counting the pill or shot.

What makes being in this study different from regular medical care?

The Truvada pill or the CAB shot may help protect you from getting HIV, but you are not being asked to take part in this study for your own medical benefit. Being in this study is different from regular medical care that you would normally receive. In regular medical care, a doctor would give you a drug that would work best for you based on your personal characteristics and medical history. In this research study, staff will randomly assign you to Group A or Group B. You will NOT be assigned to these groups because scientists believe one group will be better for you, but because scientists are comparing the drugs to see which one will be most effective for teenagers in the future.

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Please answer the following about the IMAGINARY study in your own words.

10. What makes being in this study different from regular medical care?

What if I become infected with HIV?

Being in this study will not cause HIV, but there is a chance you can get HIV through sex or other activities during the course of the study.

If you get HIV, staff will tell you to stop using the study drugs. Truvada and CAB drugs are not the usual treatment for HIV. Continuing those drugs may limit your options for HIV treatment, which is why you can't take part in this study if you have HIV and are tested for HIV at study visits.

This study can't give you general medical care, but study staff will refer you to doctors for treatment if you become infected with HIV. There are very effective treatments for HIV and most people with HIV live long and healthy lives.

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Please answer the following about the IMAGINARY study in your own words.

11. Why will you be asked to stop taking the study drugs if HIV tests show that you have been infected with HIV after you are in the study?

What are the risks of being in this study? Is there any way being in this study could be bad for me?

Risks of In-Clinic Procedures
You may feel discomfort or pain during blood draws or rectal swabs. In some cases, you may have bleeding in your rectum after a rectal swab. For both the blood draws and CAB shots, you may have a bruise, or experience swelling, a small clot, or infection where the needle goes in your arm.

Common Side Effects of Study Drugs
The most common side effects of the Truvada pill and CAB shot are nausea, diarrhea, headaches, and fatigue. These side effects are mild, don't happen in everyone, and for most people they go away after the first month of use.

Rare Side Effects of Study Drugs
There are two rare side effects of the Truvada pill. A small number (less than 1% or one in one hundred people) showed a small decrease in how their kidneys work. The other rare side effect is changes in bone mineral density (how much calcium and other minerals are in your bones which keeps them strong).

We will check your health before you join the study and during the study to reduce your chances of having any side effects. If you do have these side effects, they usually go away when you stop taking the Truvada or CAB. The doctors will monitor you and suggest extra treatment if the side effects do not disappear.

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Please answer the following about the IMAGINARY study in your own words.

12. Name one common side-effect AND one rare side effect you might experience in this study when you take CAB or Truvada drugs.

Will being in this study help me in any way?

If you take the Truvada pills daily and get the shots every 2 months, the study drugs may prevent you from getting HIV. You will get free condoms, lubricant, medical exams, sexual health counseling, and testing for HIV and STIs. If a test shows you have an STI during the study, you will get free drugs for the STI or a referral, if you need it. If a test shows you have HIV during the study, you will get a referral for treatment. This study can't give you general medical care, but study staff will refer you to another doctor for care, if needed.

Potential benefits to others
Information learned from this study may help other people as well. It may help scientists learn how to prevent teenage cisgender men and transgender women from getting HIV, the FDA decide if the drugs are safe and effective for teenagers, and teenagers get the HIV prevention drugs in the future.

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Please answer the following about the IMAGINARY study in your own words.

13. Is it possible you might not benefit from being in this study?
    - ❍ No
    - ❍ Yes
    - ❍ *I do not want to answer*

14. Name at least three potential benefits to people who participate in this study.

What happens to the information collected for the research?

We will keep your information and your medical samples in a secure place that only certain researchers have access to. This information will only be labeled with your study ID number. Your samples will be destroyed right after the test results return. Your samples and information will not be used for profit.

There are two main times we may have to break confidentiality and share your personal information with others, as required by law:

- We have to report the names of people who test positive for HIV and other STIs, because the health department requires reporting of all cases where individuals test positive for HIV/STIs. Health department workers may contact you about telling your partners so they can be tested.

- If you tell us you are hurting or planning to hurt a child, or you're planning to hurt yourself or another person, or if you are under age 18 and someone has hurt or abused you, we are required to report it to the appropriate agencies for your safety and the safety of others.

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Please answer the following about the IMAGINARY study in your own words.

15. Describe the two main times in which the researchers would have to break confidentiality and share your personal information.

Will I get paid? Will it cost me anything to participate in this research study?

If you agree to take part in this study, we will pay you $55 at each visit. There is no cost to you for study visits, study drugs, physical exams, laboratory tests or other procedures or referrals.

What if I get injured during the study?

In the unlikely event that you are injured or get sick from being in this study, please tell study staff right away. We may be able to give you emergency treatment, but you or your insurance company may be charged for this treatment. This study can't offer compensation for research-related injury.

Your parents or guardians are **not** told that you are in this study. But if you are **injured** as a result of this study and you seek treatment that is paid for by their health insurance, then it is **possible** that they may find out about you being in this study.

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Please answer the following about the IMAGINARY study in your own words.

16. Who will pay for your medical care if you are injured as a direct result of being in this study?

What happens if I do not want to be in this research?

Being in this study is completely voluntary. You have the right to refuse to be in this study. You also have the right to change your mind and stop participating in the study at any time. Nothing bad will happen to you if you do not want to be in this study. Study staff will not be able to continue to give you the HIV prevention drugs, but you can still get the medical services you would normally get at this clinic

What are the alternatives to participating in this study?

If you do not want to be in this study, you may be able to join other studies here or in the community. There may be other places where you can go for HIV counseling and testing. We will tell you about those studies and those places, if you wish.

If you decide not to participate in this study, you may also wish to consult with your regular doctor about other HIV prevention tools that are available for you.

Who can I talk to?

If you have any questions or concerns about the study, or a research-related injury, contact the research team at TeenHIVStudy@midwestresearchcollege.edu or (111) 111-1111.

The Institutional Review Board (IRB) at Midwest Research College reviewed and approved this research study. You may wish to talk to an IRB member at (111) 222-2222 or irb@midwestresearchcollege.edu for the following reasons:

- Your questions or concerns are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

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Please answer the following about the IMAGINARY study in your own words.

17. Give 2 reasons why you might want to speak to an IRB member about the study:

What else do I need to know?

When the study is over, the researchers will not be able to continue to provide you with the HIV prevention medication. However, if you would like, they will refer you to a doctor who can provide you with sexual health care.

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Thanks! You've finished reading the consent form for our hypothetical study. Next, please imagine that you are deciding whether or not to participate in this *imaginary* study.

Again, when reading though the info and answering the questions, we'd like you to pretend that you've had anal sex without condoms, if you haven't already.

Here is a copy of the form you just read. You can refer to it when you are answering the following questions, but you don't have to: [hyperlink to copy of hypothetical consent form]

18. Do you believe the purpose of this study is primarily for research purposes or primarily to provide you with the HIV prevention treatment that is best for you?
    - ❍ Primarily to provide me with the HIV prevention treatment that is best for me.
    - ❍ For research purposes & to provide me with the HIV prevention treatment that is best for me
    - ❍ Primarily for research purposes
    - ❍ *I do not want to answer*

19. Do you have to be in this study if you do not want to participate?
    - ❍ No
    - ❍ Yes
    - ❍ *I do not want to answer*

20. If you withdraw from this study, will you still be able to receive services you regularly receive from the clinic?
    - ❍ No
    - ❍ Yes
    - ❍ *I do not want to answer*

21. If you withdraw from this study, will the research staff still be able to provide you with the HIV prevention medication?
    - ❍ No
    - ❍ Yes
    - ❍ *I do not want to answer*

22. Please select the statement that best describes how you will be assigned to group A or Group B in this study
    - ❍ The researcher will place me in the group that is best for me
    - ❍ Which group I am in will be decided by chance
    - ❍ *I do not want to answer*

23. How likely is it that you would take the PrEP pill everyday while you are in the study?
    - ❍ Very unlikely
    - ❍ Somewhat unlikely
    - ❍ Somewhat likely
    - ❍ Very likely
    - ❍ *I do not want to answer*

24. How likely is it that you would come to the clinic every 2 months to get your CAB injection while you are in the study?
    - ❍ Very unlikely
    - ❍ Somewhat unlikely
    - ❍ Somewhat likely
    - ❍ Very likely
    - ❍ *I do not want to answer*

25. If you participated in the study, how much would you worry about the possible side effects of the PrEP pill?
    - ❍ None of the time
    - ❍ Rarely
    - ❍ Some of the time
    - ❍ A lot of the time
    - ❍ All of the time
    - ❍ *I do not want to answer*

26. If you participated in the study, how much would you worry about the possible side effects of the CAB shot?
    - ❍ None of the time
    - ❍ Rarely
    - ❍ Some of the time
    - ❍ A lot of the time
    - ❍ All of the time
    - ❍ *I do not want to answer*

Please answer the following questions in your own words. Again, when answering the questions, we'd like you to pretend that you've had anal sex without condoms, if you haven't already. This is because we'd like you to put yourselves in the shoes of someone who might be asked to be in a study like the one you've read about.

27. Give a reason why you might want to be in this study based on how participating might affect your life outside the study.

28. Give a reason why you might NOT want to be in this study based on how participating might affect your life outside the study.

29. Based on all the information you have been given, do you think you would choose to participate or not participate in this study?
    - ❍ I would definitely NOT choose to participate in this study
    - ❍ I would probably NOT choose participate in this study
    - ❍ I would probably choose to participate in this study
    - ❍ I would definitely choose to participate in this study
    - ❍ *I do not want to answer*

Again, put yourself in the shoes of someone who might be asked to be in this study, by imagining you've had anal sex without a condom (if you haven't already).

30. *[Participants receive based on answer to #29: would choose to participate].*
    In the question above you indicated "[pipe response chosen above]".
    *Explain why you think the potential benefits of participating are more important than the potential risks. **Be sure** to specify **both** benefits and risks in your answer.*

31. *[Participants receive based on answer to #29: would NOT choose to participate].*
    In the question above you indicated "[pipe response chosen above]".
    *Explain why you think the potential risks of participating are more important than the potential benefits. **Be sure** to specify **both** benefits and risks in your answer.*

Please rate how much you agree or disagree with each of the following statements:

Again, put yourself in the shoes of someone who might be asked to be in this study, by imagining you've had anal sex without a condom (if you haven't already).

32. If I agreed to participate in this study, I would probably regret my decision once the study began:
    - ❍ Strongly disagree
    - ❍ Somewhat disagree
    - ❍ Neither agree/disagree
    - ❍ Somewhat agree
    - ❍ Strongly agree
    - ❍ *I do not want to answer*

33. If I participated in this study, I would probably feel very anxious throughout the study:
    - ❍ Strongly disagree
    - ❍ Somewhat disagree
    - ❍ Neither agree/disagree
    - ❍ Somewhat agree
    - ❍ Strongly agree
    - ❍ *I do not want to answer*

34. If I participated in this study, I would probably feel very satisfied with the experience:
    - ❍ Strongly disagree
    - ❍ Somewhat disagree
    - ❍ Neither agree/disagree
    - ❍ Somewhat agree
    - ❍ Strongly agree
    - ❍ *I do not want to answer*