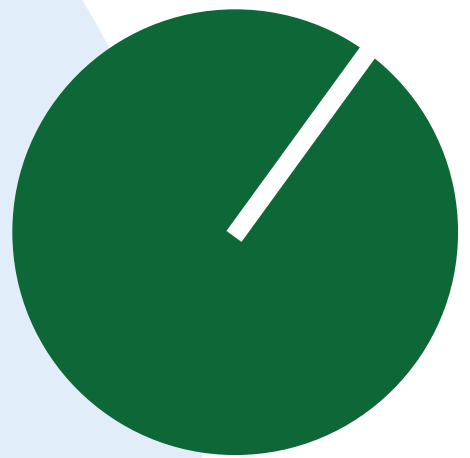


THANK YOU for
**your interest in this
important study!**

Local contact information

This international study, funded by the National Institutes of Health and other collaborating organizations, is being conducted by INSIGHT (International Network for Strategic Initiatives in Global HIV Trials) in conjunction with the Copenhagen HIV Programme (CHIP) in Denmark; the Medical Research Council (MRC) in the United Kingdom; the National Centre in HIV Epidemiology and Clinical Research (NCHECR) in Australia; the Washington International Coordinating Center in the United States; and the sponsor, the University of Minnesota.



**Timing is
everything.**



START The **S**trategic **T**iming of **A**nti**R**etroviral **T**reatment study compares the risks and benefits of starting HIV medicines at CD4+ cell counts over 500/mm³ compared to waiting until CD4+ cell counts drop to 350/mm³ in people who are well. Once treatment has started, the goal is to keep taking HIV medicines to keep the virus undetectable.

When is the best time to start taking HIV medicines? We know that HIV medicines prevent AIDS-related illnesses. These illnesses are rare when your CD4+ cell count is greater than 350/mm³.

Recent research, however, suggests that HIV-positive people who aren't taking HIV medicines may develop cancer or other illnesses affecting the heart, liver, or kidneys more than usual, even at higher CD4+ cell counts.

We need to understand whether it is better to start taking HIV medicines as soon as you know that you have HIV or to wait and follow the current guidelines.

Would starting HIV medicines earlier — that is, before CD4+ cell counts drop to below 350/mm³ — prevent serious illnesses of the heart, liver, or kidneys?

Would earlier treatment prevent more deaths?

**The START study
wants to answer
these questions.**

Two Groups

Participants in the START study will be divided into two groups: the EARLY Group and the DEFERRED group. A computer will randomly decide which of the two groups you will join. Neither you nor your doctor can choose the group that you join. Each group has special treatment rules.

EARLY Group

If you are in the EARLY Group, you will take HIV medicines immediately and will continue taking HIV medicines to keep the amount of virus in your blood as low as possible.

DEFERRED Group

If you are in the DEFERRED Group and remain well, you will NOT take HIV medicines while in the study until your CD4+ cell count drops to 350/mm³. At that time, you and your healthcare provider will choose HIV medicines that you will begin to take.

There are possible benefits (pros) and risks (cons) of being in either group.

PROS

Longer period of time at higher CD4+ cell counts

Possible protection from illnesses and complications of HIV and other causes

Decreased risk of transmitting the virus to others

CONS

More short-term and long-term side effects from HIV medicines

Higher risk that HIV medicines will not work over time because of resistance

Inconvenience of taking medicines earlier that may affect your lifestyle

PROS

Delaying side effects from HIV medicines

Waiting for newer drugs that may be better and safer

Convenience of not taking HIV medicines all the time

CONS

Longer period of time at lower CD4+ cell counts and higher viral loads

Higher risk of AIDS and other illnesses

Increased risk of transmitting the virus to others

You will be asked to remain in the group that you are assigned to. This is why, before entering the study, you need to be comfortable joining either group.



Who Can Join?

You may be eligible to join START if you:

Are at least 18 years old,

Have been diagnosed with HIV,

Have never taken any HIV medicines,

Have a CD4+ cell count of 500/mm³ or higher,

Are in general good health with no recent history of major heart, liver, or kidney disease, and

Are not pregnant or breastfeeding (for women).

If you have HIV, are healthy, and have never taken any HIV medicines, you may be eligible to be part of the START study.

If You Join

You will visit your healthcare provider 1 month after joining START and then about every 4 months afterward. You will be seen on a regular schedule by your healthcare provider for 3-6 years until the study ends.

The START study will not be testing new medicines. You and your healthcare provider will choose the HIV medicines for your treatment. If you develop side effects or your medicines no longer work during the study, your healthcare provider and you can decide to change your HIV medicines.

Will It Cost Me Anything? The START study will pay for the exams and laboratory tests that are part of the study. Your insurance or healthcare system will pay for routine costs of your healthcare. HIV medicines may be provided either by the study or by your insurance or healthcare system.

I'm Interested, Now What?

Talk to your healthcare provider about your interest in the START study.

Ask any questions that you may have.

Talk to your healthcare provider about the pros and cons of starting HIV medicines.

Check out the START participant website at www.insight-trials.org for more information.