

The START Trial: information for prospective participants

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When to start antiretroviral treatment is one of the most important outstanding questions for people with HIV and their clinicians. A large [clinical trial](#) [1]A clinical trial is a research study to answer specific questions about vaccines or new therapies or new ways of using known treatments. Clinical trials are used to determine whether new drugs or treatments are both safe and effective. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people. Trials are in four phases: Phase I tests a new drug or treatment in a small group; Phase II expands the study to a larger group of people; Phase III expands the study to an even larger group of people; and Phase IV takes place after the drug or treatment has been licensed and marketed. , **Strategic Timing of Antiretroviral Treatment (START)**, has begun and will hopefully help answer this and other important questions.

The START trial includes antiretroviral-naive HIV-positive people with CD4 counts greater than 500 cells/mm³. It is taking place at about 90 sites in nearly 30 countries, including in Australia. Participants are [randomised](#) [2]A method based on chance by which study participants are assigned to a treatment group. Randomization minimizes the differences among groups by equally distributing people with particular characteristics among all the trial arms. The researchers do not know which treatment is better. From what is known at the time, any one of the treatments chosen could be of benefit to the participant to either receive antiretroviral treatment immediately or to defer treatment until their first CD4 count less than 350 cells/mm³ or they have [clinical](#) [3]Pertaining to or founded on observation and treatment of participants, as distinguished from theoretical or basic science. signs of advanced HIV disease. Eventually, START will recruit 4000 people.

NAPWA supports the START trial and suggests that people who are eligible to participate consider volunteering to participate. The information below will help you weigh up the potential risks and benefits of participation in this research study. If you need further information, NAPWA recommends you discuss this with your treating doctor.

At present, the START trial is [enrolling](#) [4]The act of signing up participants into a study. Generally this process involves evaluating a participant with respect to the eligibility criteria of the study and going through the informed consent process. participants in **Sydney and Melbourne only**. The number of clinics participating in the trial is also limited during the pilot phase of the trial – if your regular clinic is not one of the participating trial sites, your doctor can still arrange for you to join the trial, but you will have to attend another clinic for trial-related visits.

The pilot phase of the trial is scheduled to conclude at the end of 2010. If the trial proceeds beyond the pilot phase, trial sites will be established in other cities, and a larger number of clinics in Sydney and Melbourne.

When is the best time to start taking HIV antiretroviral drugs?

We know that HIV antiretroviral drugs 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 antiretroviral drugs may develop cancer or other illnesses affecting the heart, [liver](#) [5]A large organ, located in the upper right abdomen, which assists in digestion by metabolising carbohydrates, fats and proteins, stores vitamins and minerals, produces amino acids, bile and cholesterol, and removes toxins from the blood., or kidneys more than usual, even at higher CD4+ cell counts. We need to understand whether it is better to start taking HIV antiretroviral drugs as soon as you know that you have HIV or to wait and follow the current guidelines.

Would starting HIV antiretroviral drugs 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 antiretroviral drugs immediately and will continue taking HIV antiretroviral drugs to keep the amount of [virus](#) [6]A small infective organism which is incapable of reproducing outside a host cell. in your blood as low as possible.

Deferred group

If you are in the **DEFERRED group** and remain well, you will NOT take HIV antiretroviral drugs while in the study until your CD4+ cell count drops to 350/mm³. At that time, you and your doctor will choose HIV antiretroviral drugs that you will begin to take.

Risks and benefits

There are possible benefits and risks of being in either group. 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.

Early group

Deferred group

Possible **benefits**:

- 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

Possible **benefits**:

- Delaying side effects from HIV antiretroviral drugs
- Waiting for newer drugs that may be better and safer
- Convenience of not taking HIV antiretroviral drugs all the time

Possible **risks**:

- More short-term and long-term side effects from HIV antiretroviral drugs
- Higher risk that HIV antiretroviral drugs will not work over time because of [resistance](#)
- Inconvenience of taking medicines earlier that may affect your lifestyle

Possible **risks**:

- 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

Who can join?

If you have HIV, are healthy, and have never taken any HIV antiretroviral drugs, you may be eligible to be part of

the START study.

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 antiretroviral drugs;
- 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 join

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




The START study will not be testing new HIV [antiretrovirals](#) [8] A medication or other substance which is active against retroviruses such as HIV.. You and your doctor will choose the HIV antiretroviral combination best for you from the HIV drugs already available in Australia. If you develop side effects or your medicines no longer work during the study, you and your doctor can decide to change your HIV antiretroviral drugs.

Will it cost me anything?

The START study will cover any costs associated with the study monitoring and laboratory tests that are part of the study. This also includes the costs of the HIV drugs you take while on the study, and any logistical costs for extra visits to your clinic site.

I'm interested, now what?

- Talk to your doctor about your interest in the START study.
- Ask any questions that you may have.
- Talk to your doctor about the pros and cons of starting HIV antiretroviral drugs.
- Check out the [START participant website](#) [9] for more information.

Attachment	Size	Type
START Participant Brochure [10]	97.83 KB	 PDF
START Pros and Cons and Eligibility Criteria [11]	44.2 KB	 PDF
Community Statement on the START trial and the change in the US DHHS treatment guidelines [12]	102.03 KB	 PDF

- [clinical trials](#)
- [Other fact sheets](#)
- [starting treatments](#)

Links:

- [1] <http://www.napwa.org.au/glossary/term/89>
- [2] <http://www.napwa.org.au/glossary/term/513>
- [3] <http://www.napwa.org.au/glossary/term/475>
- [4] <http://www.napwa.org.au/glossary/term/489>
- [5] <http://www.napwa.org.au/glossary/term/102>

[6] <http://www.napwa.org.au/glossary/term/125>

[7] <http://www.napwa.org.au/glossary/term/109>

[8] <http://www.napwa.org.au/glossary/term/122>

[9] <http://www.insight-trials.org>

[10] http://www.napwa.org.au/files/START_Participant_Brochure.pdf

[11] http://www.napwa.org.au/files/STARTpros-cons_and_elig-July2-version2.pdf

[12] <http://www.napwa.org.au/files/CABStatementOnSTART.pdf>