

## START (Strategic Timing of AntiRetroviral Treatment)

From the NAPWA website at <http://www.napwa.org.au/trials/start-strategic-timing-of-antiretroviral-treatment>

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### Clinical trials information

## START (Strategic Timing of AntiRetroviral Treatment)

This trial is **enrolling now**. Depending on eligibility and available places in your area, you may be able to enrol in this trial.

### About this trial

This international, [randomised](#) 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. Study aims to determine the most appropriate time to start treatment: when T-cell counts are above 500 or, as is the current recommendation, when they drop to 350.

All participants will be treatment naive with counts above 500 cell/mm<sup>3</sup> and will be randomised to either receive immediate treatment or wait until their counts drop to 350 (or they develop an AIDS-defining condition).

### Background information

Currently, starting antiretroviral treatment is usually only recommended when your T-cell count falls to around 350 cells/mm<sup>3</sup>. (Normal range is 500-1200).

With certain exceptions, treating earlier than this is considered unnecessary for a number of reasons. It prolongs your risk of developing longterm complications from the drugs. It's more likely you'll get tired of taking pills, miss doses and develop resistance. It's more expensive.

However, there's some data which suggests that treating earlier might in fact be a good idea. Recent studies compared treaters with non-treaters at identical cell counts and found that the risk of developing an AIDS-defining condition was higher for the non-treaters even when their counts were well above 500 cells/mm<sup>3</sup>.

T-cell counts have always been an important clinical marker. Certainly, higher counts reduce the risk of developing serious AIDS-related conditions (like PCP) and non-AIDS-related conditions (such as cardiovascular disease). But we're starting to question whether there's more going on than can be assessed simply by counting T-cells.

### NAPWA commentary

NAPWA has a separate fact sheet that outlines the issues relating to this trial. It can be found [here](#).

#### Official title:

Strategic Timing of AntiRetroviral Treatment (START)

#### What is this trial studying?

tx\_strategy

#### Start date:

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Mid 2009 (This may be the proposed or expected start date for trials which have not yet started.)

### **How many participants will this trial enrol?**

900 (The exact number of participants may be lower or slightly higher than this. Some trials also have specific quotas for participants from each state, city or clinic.)

### **How long is this trial planned to go for?**

Participants in this trial will be asked to follow the treatment strategy for 5 years.

### **Links to further information:**

- <http://insight.cabr.umn.edu/start/>
- <http://clinicaltrials.gov/ct2/show/NCT00867048?term=START+AND+HIV&rank=3>

### **Who can enrol in this trial?**

You *may* be eligible to participate in this trial if you meet the following criteria:

- At least 18 years old
- HIV-positive
- Have never taken HIV treatments
- CD4 count at least 500 cells/mm<sup>3</sup>

This is a summary of key inclusion and exclusion criteria for this trial. There may be other criteria which may exclude some people from participation in this trial. Some laboratory tests may also be required. Consult your doctor, or view the trial protocol or informed consent documentation to see the full range of exclusion and inclusion criteria.

### **If you are interested in enrolling in this trial**

Before making the decision to participate in any clinical trial, NAPWA recommends that you discuss the potential benefits and risks of participation with your treating doctor. Your doctor can also provide advice about your eligibility to participate in the trial.

While NAPWA has taken every care to compile the information on this page and to keep it up-to-date, we cannot guarantee its correctness and completeness.

Before making the decision to participate in any clinical research, visit the NAPWA website for background information on participating in clinical research.

Contact NAPWA if you have any questions or comments about this trial.