

Clinical trials information

ALTAIR (Truvada for treatment-naive)

This trial is **concluded**. This means the trial has been completed. The results of the trial are summarised in the 'results' section of this page. You cannot enrol in this trial.

About this trial

This is a [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 which compares three different possible starting combinations of antiretrovirals. Everyone in the study will receive a fixed-dose combination pill containing tenofovir plus emtricitabine (Truvada) with either efavirenz, atazanavir/r (the small 'r' means with a low dose of ritonavir) or AZT plus abacavir.

Each group will be compared to see which combinations are easy to take, which ones carry side effects and which ones are most effective against HIV.

UPDATE:

Data collected from the study week 48 analysis demonstrated that [Arm](#)Any of the treatment groups in a randomised trial. Most randomised trials have two "arms," but some have three "arms," or even more. III (AZT plus abacavir) was inferior to Arms I and II in terms of plasma [viral load](#)A measurement of the quantity of HIV RNA in the blood. Viral load blood test results are expressed as the number of copies (of HIV) per milliliter of blood plasma. and other measures of virological [efficacy](#)(Of a drug or treatment). The maximum ability of a drug or treatment to produce a result regardless of dosage. A drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed. In the standard procedure, Phase II clinical trials gauge efficacy, and Phase III trials confirm it.. Because of this, it has been advised that, at the physician's discretion, patients switch to either Arm I or II and that patients on Arms I and II will remain on the current study drugs.

There was also a [protocol](#)A study plan on which all clinical trials are based. The plan is carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants following a protocol are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment amendment to include one extra safety follow up visit at week 144 for all patients, regardless of treatment arm or current treatment.

NAPWA commentary

NAPWA has expressed some ongoing views about this study, which we have discussed in detail with the National Centre in HIV Epidemiology and Clinical Research.

Primarily, we raised concerns about the use of AZT in one of these arms as a first-line HIV treatment. AZT has been associated with lipodatrophy - the loss of fat from the face or limbs which can lead to changes in your physical appearance. Research has shown that for some people, AZT can cause this condition after 12 months of being on the drug.

In general, HIV guidelines and treating doctors encourage people to look at alternatives to AZT for their first antiretroviral regimen. Combinations are available which are easy to take and are not associated with this problem.

ALTAIR (Truvada for treatment-naive)

From the NAPWA website at <http://www.napwa.org.au/trials/altair-truvada-for-treatment-naive>

In this study, you would have a one in three chance of being randomly selected to start with AZT. Further, you would be receiving four treatments from the same class of drugs, which is a departure from the guidelines for first-line therapy which recommend using drugs from at least two classes.

In the study's favour, the researchers note it may provide good evidence that a combination using only one class of treatments may be effectively used in first-time combinations - which would be useful information especially in countries where there are fewer treatment options.

There are a range of important issues relating to entering clinical studies, especially when you have never taken HIV antiretroviral treatment before. A discussion of these issues can be found here on this website.

Official title:

A Randomised Open-Label Study Comparing the Safety and Efficacy of Three Different Combination Antiretroviral Regimens as Initial Therapy for HIV Infection

What is this trial studying?

tx_strategy – atazanavir, zidovudine (AZT), efavirenz, abacavir, Truvada

Start date:

Mid 2007 (This may be the proposed or expected start date for trials which have not yet started.)

How many participants will this trial enrol?

300 (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 2 years. Following the conclusion of the trial, participants will be followed up for a further 1 years.

Links to further information:

- <http://clinicaltrials.gov/ct2/show/NCT00335322?term=ALTAIR&rank=1>
- <http://www.altair-study.com/home.html>

Who can enrol in this trial?

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

- At least 16 years old
- Have never taken HIV treatments
- CD4 count at least 50 cells/mm³
- Viral load at least 2000 copies/ml

You *will not* be eligible to participate in this trial if you meet any of the following criteria:

- HIV which is resistant to the study drugs
- Sensitivity or the possibility of allergic reaction to any of the drugs

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.

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From the NAPWA website at <http://www.napwa.org.au/trials/altair-truvada-for-treatment-naive>

Results:

The trial will conclude in mid 2010.

The week 48 data were presented as a late breaker poster at the International AIDS Society meeting in July 2009 in Cape Town. Follow this link : <http://www.ias2009.org/pag/PDF/3799.pdf>.

Also see main findings in the two papers attached.

Disclaimer

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.