

Clinical trials information

SPARTA

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 study is looking at how safe and effective it is to treat HIV with a combination of just two drugs: raltegravir and atazanavir. The study will compare once-daily with twice-daily doses of the drugs.

Background information

Current HIV treatment guidelines recommend combination regimens comprising a minimum of three agents from at least two drug classes. There are problems with the current recommendations because although treatments are effective, their success is often limited by tolerability, adverse effects and the need to take many pills.

Antiretroviral adherence remains vital and regimens should be simplified wherever possible to facilitate maximal adherence.

The recent availability of raltegravir from the new class of integrase inhibitors provides an opportunity to explore moves away from current regimen components.

Evidence to support the use of novel regimens must be generated through adequately powered randomised clinical trials. However, before such trials can be undertaken, preliminary data to define the pharmacokinetics, safety and tolerability of these regimens are needed to minimise unnecessary risk for participants. This eight week study will investigate the short-term safety and efficacy of two dosing strategies (once and twice daily) of raltegravir plus atazanavir in treatment experienced people.

NAPWA commentary

An optional component of this study is volunteering to donate a sample of your semen and/or spinal fluid. The purpose of this is so they can compare the viral load and quantity of drug in your blood sample with that in samples of other body fluids to see if there is any difference. While this is an important component of this study it is definitely not compulsory.

Official title:

A Randomised, Open-Label, Cross-Over Study to Examine the Pharmacokinetics and Short-Term Safety and Efficacy of Two Dosing Strategies of Raltegravir Plus Atazanavir in HIV-Infected Patients

What is this trial studying?

tx_strategy – atazanavir, raltegravir

Start date:

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

How many participants will this trial enrol?

SPARTA

From the NAPWA website at <http://napwa.org.au/trials/sparta>

24 (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 8 weeks.

Links to further information:

- <http://clinicaltrials.gov/ct2/show/NCT00874523>

Can I access this treatment other than by enrolling in this trial?

Both raltegravir and atazanavir are available through the PBS.

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
- Currently taking HIV treatments
- currently receiving atazanavir as part of combination therapy for at least 6 months

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.

Results:

In virologically suppressed adults, regimens comprising ATV plus RAL were efficacious and safe. See attachment for full report

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.