Clinical trials information

Second line

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

A treatment regimen consisting of one non-nucleoside (1NNRTI) and two nucleosides (2NRTIs) has become the internationally accepted first-line therapy of choice. But effective as the combination is, it doesn't work for everyone. And those it fails need a reliable back-up. At the moment there is no "internationally accepted" second-line.

This trial will enrol people in both resource-limited and resource-rich countries (including Australia) whose first-line "1NNRTI+2NRTIs" ceased to work. Half will be put on a regimen containing a boosted protease inhibitorA type of anti-HIV drug that works by preventing the production of an enzyme, protease, that HIV needs to replicate. plus 2NRTIs. The other half will be on a boosted protease inhibitor plus raltegravir (from the new drug class of integrase inhibitors).

Investigators will then be able to assess which of these "second-line" combinations is safer, easier to take and better at controlling HIV.

Background information

A reliable and robust second-line treatment option is vital, particularly for those living with HIV in resource poor settings. CD4 counts and physical diagnosis are often the only monitoring methods available. By the time it has been established that the first-line therapy has failed, the situation is often life-threatening and so it is imperative that the second-line does not fail.

Official title:

A Randomised Open-label Study Comparing the Safety and Efficacy of Ritonavir Boosted Lopinavir and 2-3N(t)RTI Backbone Versus Ritonavir Boosted Lopinavir and Raltegravir in Participants Virologically Failing First-line NNRTI/2N(t)RTI Therapy

What is this trial studying?

tx_strategy – raltegravir

Start date:

Early Januarary 2010 (This may be the proposed or expected start date for trials which have not yet started.)

How many participants will this trial enrol?

480 (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 96 weeks.

Links to further information:

- http://clinicaltrials.gov/ct2/show/NCT00931463?term=second-line&rank=5
- http://www.anzctr.org.au/trial_view.aspx?ID=320665

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

All drugs being trialled are currently available on 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
- Have taken HIV treatments in the past
- must have failed a first-line therapy containing one NRTI plus two NNRTIs, no prior exposure to protease inhibitors or integrase inhibitors

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

- You must not have hepatitis B (HBV)

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:

This study found that the raltegravir (Isentress) based combination was as effective as the currently recommended treatment combinations for people taking 'second line' combinations (for people who have developed resistance to their first combination). The raltegravir combination also found to be safe and well tolerated. This simple treatment strategy might extend the current approach to the treatment of HIV by providing a simple, easy to administer, effective, safe and well tolerated second-line treatment combination. The absence of the need for resistance testing or to follow algorithms (complex calculations) for selection of NtRTI backbones, as well as the tolerability of the raltegravir based combination support the use of this combination in second line treatment.

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.