Clinical trials information

VERxVE (fast and slow release nevirapine)

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 two versions of the same drug - nevirapine - and comparing the effectiveness(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. and safety of one that releases the drug over a long period against one that does so immediately.

It's a double-blindA clinical trial design in which neither the participating individuals nor the study staff knows which participants are receiving the experimental drug and which are receiving a placebo (or another therapy). Double-blind trials are thought to produce objective results, since the expectations of the doctor and the participant about the experimental drug do not affect the outcome; also called double-masked study./double-dummy trial so no-one knows who's on which version of the drug - the slow release one or the immediate release one. Everyone will be put on the same background regimen - Truvada (tenofovir-emtracitabine).

You need to be treatment naive to enrol.

Background information

Nevirapine is one of four non-nucleoside reverse transcriptase inhibitors (NNRTIs) available in Australia (efavirenz, delarvirdine and etravirine are the other PBS approved drugs).

The NNRTIs work by binding directly to the reverse transcriptase enzyme, thereby interfering with its activity.

When HIV infects a CD4 cell in a person's body, it copies its own genetic code into the cell's DNA. In this way, the cell is then 'programmed' to create new copies of HIV. HIV's genetic material is in the form of RNA. In order for it to infect CD4 cells, it must first convert its RNA into DNA. HIV's reverse transcriptase enzyme is needed to perform this process.

NNRTIs, also known 'non-nukes' attach themselves to reverse transcriptase and prevent the enzyme from converting RNA to DNA. In turn, HIV's genetic material cannot be incorporated into the healthy genetic material of the cell, and prevents the cell from producing new virus.

All drugs in this family have similar side effect profiles - rash being the most common (see Nevirapine Toxicogenomics Study).

Official title:

A Randomised, Double Blind, Double Dummy, Parallel Group, Active Controlled Trial to Evaluate the Antiviral Efficacy of 400 mg QD Nevirapine Extended Release Formulation in Comparison to 200 mg BID Nevirapine Immediate Release in Combination With Truvada? in Antiretroviral Therapy Naive HIV-1 Infect

What is this trial studying?

Information on the NAPWA website is provided subject to conditions of use that can be view at napwa.org.au. Visit the website for updated versions of this information.

tx_strategy – nevirapine, Truvada

How many participants will this trial enrol?

1033 (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 48 weeks.

Links to further information:

- http://clinicaltrials.gov/ct2/show/NCT00561925?term=Boehringer+AND+HIV&cntry1=PA%3AAU&rank=2

Related trials:

- (http://napwa.org.au/node/)

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

Nevirapine in its standard form is an approved drug.

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 never taken HIV treatments
- CD4 count between 50 and 400 cells/mm^3
- Viral load at least 1000 copies/ml

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

- Have active hepatitis B or C

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:

August 2010 update: Interim results from the VERxVE study were presented last month at the 18th International AIDS Society (IAS) conference in Vienna, Austria, and showed that once daily nevirapine extended release (XR) formulation (400mg QD) Viramune(r) is non-inferior to the currently used twice daily immediate release (200mg BID) Viramune(r) (IR) through 48 weeks. The 400mg QD nevirapine extended release formulation (Viramune(r) XR) demonstrated adequate trough drug exposure through 48 weeks, and efficacy was consistent across gender, baseline viral load and country of origin. Both formulations demonstrated a similar adverse event profile and no new side effects were identified. The primary endpoint for VERxVE was confirmed virological response through 48 weeks of treatment, with response defined as a viral load of

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