Clinical trials information

ENCORE-1

This trial is **fully enrolled**. This means that all of the available places on the trial have been filled. You cannot enrol in this trial.

About this trial

This study will compare the safety and 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. of using a lower dose of efavirenz - 400mg versus the standard 600mg dose currently prescribed.

Participants will be randomisedA 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 to receive either dose along with Truvada (tenofovir + emtricitabine) and be followed for 96 weeks.

Participants will have an equal (1:1) chance of receiving either regimen. This is 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. study so neither participant nor the doctor will be aware of which treatment participants receive.

Background information

There's evidence to suggest that several antiretrovirals might be just as effective when taken in doses lower than they're currently prescribed. Potentially, this could mean paying less for fewer pills with not as many side effects or toxicities.

This is one of several trials looking at finding the optimum dose of various antiretrovirals. Other trials will be looking at ritonavir, ritonavir-boosted lopinavir, ritonavir-boosted atazanavir, and zidovudine.

Official title:

A Randomised, Double-blind, Placebo-controlled, Clinical Trial to Compare the Safety and Efficacy of Reduced Dose Efavirenz (EFV) With Standard Dose EFV Plus Two Nucleotide Reverse Transcriptase Inhibitors (N(t)RTI) in Antiretroviral-naïve HIV-infected Individuals Over 96 Weeks

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 – efavirenz

Start date:

March 2011 (This may be the proposed or expected start date for trials which have not yet started.)

How many participants will this trial enrol?

630 (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/NCT01011413?term=ENCORE-1&rank=1

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 500 cells/mm^3
- Viral load at least 1000 copies/ml

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.

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.

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