

Clinical trials information

UK-453, 061

This trial is **concluded**. This means the trial has been completed. When the results of the trial have been made public, they will be summarised in the 'outcomes' section of this page. You cannot enrol in this trial.

About this trial

UK-453, 061 (Iersivirine) is a second generation NNRTI (or non-nuke).

In [Phase I](#) clinical trial designed to establish whether an experimental drug is safe for humans to take. Phase I studies determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and look for early evidence of effectiveness; these studies may include either people with HIV, HIV-negative volunteers, or both trials it proved to be effective against mutations of HIV which were [resistant](#) HIV which has mutated and is less susceptible to the effects of one or more anti-HIV drugs is said to be resistant. to first generation NNRTIs, like nevirapine and efavirenz.

In this [Phase II](#) A smaller clinical trial designed to establish whether a drug is effective. Phase II studies are conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks. If there is evidence that the drug is effective, a Phase III study is undertaken, with a larger number of participants, to confirm this. trial they want to test different doses of the drug to see which is the safest and most effective. They also want to compare how well it works against efavirenz, so some of the people in the study will receive UK-453, 061 plus Truvada and the others will receive efavirenz plus Truvada.

NB: Truvada contains the 2 nucleosides tenofovir and emtricitabine.

Background information

NNRTIs form the backbone of many people's treatment regimens. Currently there are only three approved drugs available in this class - nevirapine and efavirenz being the two most prescribed - and people often develop resistance to one or both of them. Other experimental NNRTIs also being trialed include rilpivirine and etravirine.

Official title:

A Study Of Different Doses Of UK-453, 061 Plus Truvada Compared To Efavirenz Plus Truvada In Patients Who Have Not Been Previously Treated For HIV-1

What is this trial studying?

new_drug – efavirenz, Truvada, UK-453,061

Start date:

February 2009 (This may be the proposed or expected start date for trials which have not yet started.)

How many participants will this trial enrol?

189 (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 take the trial drugs for 96 weeks.

Links to further information:

- <http://clinicaltrials.gov/ct2/show/NCT00824421?term=HIV+AND+Australia&rank=50>
- <http://clinicaltrials.gov/ct2/show/NCT00824369?term=HIV+AND+Australia&rank=64>

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

Expanded access is available which means anyone who drops out of the trial can still receive the 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
- HIV-positive
- CD4 count at least 200 cells/mm³
- 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.