

## Clinical trials information

### DUET study (etravirine)

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

Etravirine (TMC 125) is an [experimental](#) (Of a drug) Not licensed for use in humans, or as a treatment for a particular condition. Experimental drugs are studied in clinical trials to determine their safety and efficacy, and are sometimes made available via Special Access Schemes prior to their approval. non-nucleoside reverse transcriptase inhibitor (NNRTI). This trial is to study the safety and tolerability of this treatment, and its [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. against HIV.

The trial is [randomised](#) A 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 and people take either etravirine in combination with an optimized background regimen or a combination without etravirine.

#### Background information

The non-nucleoside reverse transcriptase inhibitor class of antiretrovirals is a very important one. The two most common drugs in this class, nevirapine and efavirenz, are widely used because they are extremely effective in fighting HIV.

The downside is that HIV can develop resistance to this class fairly easily. And resistance to one drug in this class means resistance to all of them.

For this reason, it has been a major goal of drug researchers to develop a NNRTI that HIV will find hard to resist and one which can still be used even when nevirapine and efavirenz no longer work.

Etravirine (TMC 125) has been engineered with this task in mind. It is hoped that the studies will show that this drug works well against HIV and provides a new treatment option in this class.

#### Official title:

A Phase III Randomised, Double-Blinded, Placebo-Controlled Trial to Investigate the Efficacy, Tolerability and Safety of TMC125 as part of an ART Regimen, Including TMC114/RTV and an Investigator-Selected OBR, in HIV-1 Infected Patients with Limited Treatment to No Treatment Options

#### What is this trial studying?

new\_drug – etravirine (TMC-125)

#### Start date:

## **DUET study (etravirine)**

From the NAPWA website at <http://www.napwa.org.au/trials/duet-study-etravirine>

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Oct 2005 (This may be the proposed or expected start date for trials which have not yet started.)

### **How long is this trial planned to go for?**

Participants in this trial will be asked to take the trial drug for 48 weeks. Following the conclusion of the trial, participants will be followed up for a further 4 weeks.

### **Links to further information:**

- [http://www.hivandhepatitis.com/2008icr/croi/docs/020808\\_d.html](http://www.hivandhepatitis.com/2008icr/croi/docs/020808_d.html)

### **Related trials:**

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

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

Etravirine is now 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
- Currently taking HIV treatments
- Demonstrated resistance to multiple HIV drugs and/or drug classes
- Viral load at least 5000 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.

### **Results:**

In the DUET trials conducted at London's Chelsea and Westminster Hospital, investigators have found that etravirine is effective against resistance mutations in patients who had experienced an increase in viral load to detectable levels using the existing NNRTIs, efavirenz or nevirapine. In the trial of 743 patients, investigators found that 89% who had resistance after treatment with nevirapine were susceptible to etravirine and 91% of patients whose virus was resistant to efavirenz would benefit from treatment with the new drug.

See Link above for summary of 48 week data.

### **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.