

CCR5 inhibitor trial: maraviroc (treatment experienced)

From the NAPWA website at <http://www.napwa.org.au/trials/ccr5-inhibitor-trial-maraviroc-treatment-experienced>

Clinical trials information

CCR5 inhibitor trial: maraviroc (treatment experienced)

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 is an ongoing trial of 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. HIV antiviral from a new class of drugs, known as 'entry inhibitors'. Entry inhibitors work by trying to prevent HIV from attaching to or being able to enter and infect cells.

The drug in this trial, maraviroc, is called a CCR5 inhibitor, and is designed to prevent HIV from attaching to specific 'receptors' on the surface of human immune cells. If HIV can't attach to the cell, it can't infect it (see Background Info for more discussion). The particular cell 'marker' which HIV uses to attach to a cell is called CCR5.

This drug aims to prevent HIV from being able to use this to attach to and then get into cells. This is a [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 study, and compares the experimental treatment, maraviroc, against a treatment combination selected from available licensed treatments. All people on the study receive either maraviroc OR a treatment using a combination of three already-licensed HIV [antivirals](#) A medication or substance which is active against one or more viruses. May include anti-HIV drugs, but these are more accurately termed antiretrovirals.. In a third [arm](#) Any of the treatment groups in a randomised trial. Most randomised trials have two "arms," but some have three "arms," or even more. of the study, people receive currently available antiviral treatment, but the choice of drugs has been determined with [resistance](#) HIV which has mutated and is less susceptible to the effects of one or more anti-HIV drugs is said to be resistant. testing. The study is comparing the maraviroc with the two other arms, looking at how effective each is against HIV, and comparing them for safety and side effects.

Background information

For HIV to enter and infect your body's CD4 cells (T-cells), it first has to attach itself to them. HIV does this by using a marker on the surface of your CD4 cells, called a chemokine receptor. A chemokine receptor is basically a kind of protein or chemical messenger.

HIV attaches itself to this chemokine receptor and from there, is able to get into the CD4 cells and take them over. There are two main chemokine receptors to which HIV usually attaches itself. They are known as CCR5 and CXCR4. This study is looking at whether by using a new drug designed to prevent HIV from attaching itself to the CCR5 receptor of CD4 cells you can control HIV by stopping it from being able to infect new cells.

Official title:

Trial of Maraviroc (UK-427,857) in Combination With A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of a Novel CCR5 Antagonist, UK-427,857, in Combination With Optimized Background Therapy Versus Optimized Background Therapy Alone for the Treatment of Antiretroviral-Experienced HIV-1 Infected Subjects

CCR5 inhibitor trial: maraviroc (treatment experienced)

From the NAPWA website at <http://www.napwa.org.au/trials/ccr5-inhibitor-trial-maraviroc-treatment-experienced>

What is this trial studying?

new_drug – maraviroc

Start date:

December 2004 (This may be the proposed or expected start date for trials which have not yet started.)

How many participants will this trial enrol?

500 (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.)

Links to further information:

- <http://clinicaltrials.gov/ct2/show/NCT00098722?term=Pfizer+AND+CCR5&cntry1=PA%3AAU&rank=2>
- http://www.clinicalstudyresults.org/documents/company-study_3759_0.pdf

Related trials:

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

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

Maraviroc is available in Australia through the Special Access Scheme until it becomes an approved s100 drug through the Pharmaceutical Benefits Scheme (PBS)

Who can enrol in this trial?

You *may* be eligible to participate in this trial if you meet the following criteria:

- At least 16 years old
- Have taken HIV treatments in the past
- Demonstrated resistance to multiple HIV drugs and/or drug classes
- Viral load at least 5000 copies/ml
- Documented resistance to at least three of the existing classes of antiviral treatment, or other evidence of extensive treatment experience

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:

See link above for Clinical Study Results.

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.

CCR5 inhibitor trial: maraviroc (treatment experienced)

From the NAPWA website at <http://www.napwa.org.au/trials/ccr5-inhibitor-trial-maraviroc-treatment-experienced>
