

Clinical trials information

STEP HIV vaccine study

This trial has been **cancelled**. Clinical trials may be cancelled prior to commencement, or during the course of the trial, for a number of reasons – these may be summarised below. You cannot enrol in this trial.

About this trial

This is a study of a vaccine with the potential to prevent HIV infection. Unlike other studies listed on this site it is only open to people who are HIV negative.

This is an early-stage study. It is not aiming to prove that the vaccine will prevent HIV in large numbers of people, but rather that it (1) is safe and well-tolerated and (2) may provide some evidence that it EITHER reduces the number of people who acquire HIV or can prevent people from developing any illness resulting from exposure to HIV.

The [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 vaccine will be tested against a [placebo](#) A dummy medical treatment, designed to have no pharmacological effect, administered to the control group of a clinical trial. or 'dummy pill'. Both are administered by injection so people in the study will not know whether they are receiving the vaccine or not.

Background information

Most vaccines are designed to prevent you from actually becoming infected with a particular virus or bacteria. They are designed so that the immune system attacks the invading virus or bacteria, and 'neutralises' it so it cannot infect your body. This sort of vaccination has proven extremely hard to develop in HIV and so an alternative approach has been developed.

The vaccine in this study uses synthetic or 'manufactured' parts of HIV's genetic material and introduces them into the body's cells by 'piggybacking' them on a completely different, harmless virus. The theory is that this will stimulate the body to produce an army of killer T-cells which will seek out and destroy any cells infected with these HIV genes. The body would then 'remember' its response so that later, if a person did actually get exposed to HIV, the body would have a planned response and be ready to eliminate any of the cells infected with HIV.

There is an important limitation to this experimental approach. It is possible that it will not prevent people from becoming infected with HIV but will assist the immune system to keep HIV under control over the longer term so that it cannot go on to cause disease. The point of this trial is to see if this is so.

There is no guarantee in this trial that you will be receiving the vaccine or that the vaccine can prevent you from getting HIV.

NAPWA commentary

There are very serious issues to consider when entering a placebo-controlled vaccine study. Most important is to understand that there is no guarantee that this vaccine will either prevent you from getting HIV or prevent HIV from

STEP HIV vaccine study

From the NAPWA website at <http://www.napwa.org.au/trials/step-hiv-vaccine-study>

being able to cause illness if you do become infected.

The trial has been approved because there is so far good evidence that the vaccine may either prevent HIV or delay or prevent HIV-related illness, but this has not been proven. This study is part of the process of collecting the evidence.

At least one vaccine using a similar approach has already been trialed in Sydney and did not produce the immune responses which would be needed for an effective vaccine of this sort. There is some evidence that this current vaccine may be effective but this is not known. It is also important to realise that you may be randomised to receive the placebo or 'dummy' injections.

If you are accepted into this study, it is because you, your doctor and the trial organisers have agreed that, because of your current life circumstances or behaviours, you are at high risk of exposure to HIV.

The definition used to work out whether you are at 'high risk' has been made using current Australian research about risk of HIV transmission. The definition includes: Women and men who have an HIV positive regular sexual partner; Women and men who have ever taken non-occupational PEP (post-exposure prophylaxis); Men who have had unprotected anal sex in the last six months; and Men who have had an anal sexually transmissible infection in the last year.

You should not make decisions about your HIV risk or behave differently on the assumption that you will be 'vaccinated' or 'protected' against HIV during or after this trial.

HIV infection can be prevented by always using condoms and lubricant when having anal or vaginal sex and by always using new equipment when injecting drugs. For further information about preventing HIV contact your local AIDS council or PLWHA group.

This study will also collect further information about the safety of the experimental vaccine. There may be other, non-HIV related risks from taking this vaccine, which may include: pain, swelling or reactions at the injection site, headache, or a range of immune responses common to many vaccines, including flu-like illness, joint pain or swelling, fever and diarrhoea.

Official title:

A multicentre, Double-Blind, Randomised, Placebo-Controlled Phase II Proof-of-Concept Study to Evaluate the Safety and Efficacy of a 3-Dose Regimen of the Merck Adenovirus Serotype-5 HIV-1 Vaccine gag/pol/nef (MRKad5 HIV-1 gag/pol/nef in Adults at High Risk of HIV-1 Infection

What is this trial studying?

vaccine

Start date:

1 May 2006 (This may be the proposed or expected start date for trials which have not yet started.)

How many participants will this trial enrol?

100 (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://www.afao.org.au/view_articles.asp?pxa=ve&pxs=163&id=574
- <http://www.hvtn.org/science/step.html>

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From the NAPWA website at <http://www.napwa.org.au/trials/step-hiv-vaccine-study>

<http://clinicaltrials.gov/ct2/show/NCT00051454?term=HIV+AND+Australia&rank=74>

<http://www.ncbi.nlm.nih.gov/pubmed/16511428?dopt=Abstract>

<http://aidsmap.org/en/news/E30B88ED-2A6C-44D3-9AF6-61DB62FD9D0D.asp>

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

No. This is an unlicensed and experimental agent, and is not available outside trials.

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
- HIV negative
- At high risk of HIV infection (this is defined by the trial protocol, using specific criteria, which you will need to discuss with your doctor and the trial team)

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:

The STEP study was closed following people taking the vaccine contracting HIV for reasons that are being investigated. Patients who participated in this trial are continuing to be monitored [and will conclude at end the of December 2009](#).

A summary of the current situation: <http://aidsmap.org/en/news/E30B88ED-2A6C-44D3-9AF6-61DB62FD9D0D.asp>

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.