

Briefing on forthcoming 'preventive' HIV vaccine trial for community organisations

What's going on?

A new trial of an experimental HIV vaccine will be announced in May 2006. The trial is known as the Step Study.

What is the Step Study?

In mid-May 2006 an HIV vaccine trial known as 'the Step Study' will begin recruitment in Sydney.

The STEP Study is designed to test whether an experimental HIV vaccine provides any protection from HIV infection or disease and to gather information about the safety profile of the vaccine.

Sydney is one of multiple trial sites, which include various cities in the US, Canada, South America and the Caribbean.

Who can go on the trial?

The trial is looking for volunteers living in Sydney aged between 18 and 45 who are at very high risk of HIV acquisition. 'Very high risk' has been defined using most recent data on people most likely to seroconvert, largely drawn from the HIM (Health in Men) study. The inclusion criteria are:

- Men and women who have an HIV positive regular sexual partner;
- Men and women who have ever used PEP (post-exposure prophylaxis) in for a sexual exposure;
- Men who have had unprotected anal sex in the last six months; or
- Men who have had an anal sexually transmissible infection in the last six months.

Some specific criteria for eligibility based on medical history also apply.

The timeline

The media announcement of the vaccine trial is scheduled for Tuesday April 11. People interested in participation will be invited to contact the National Centre in HIV Epidemiology and clinical research for further information.

How is the trial designed?

The trial is randomised, placebo-controlled and double-blinded. This means that half of the participants will be randomly selected to receive the active experimental vaccine and half will receive an inactive substance (placebo) that looks like the vaccine. Neither participants nor the trial doctors will know who gets active vaccine and who gets the placebo.

Will the vaccine provide protection from HIV?

There is no evidence that the experimental vaccine offers any protection from HIV. There are three possibilities: that the vaccine will have no effect; that the vaccine will prevent HIV (considered unlikely); or that the vaccine will not prevent infection, but might delay the onset of HIV disease.

If the vaccine delays AIDS rather than prevents infection, is it a therapeutic vaccine?

No. This trial is designed to test the vaccine in HIV *negative* people. If it does not prevent infection, however, but delays progression to AIDS it would be called a *partially effective vaccine*.

A separate trial that looks at how a closely related vaccine works in people with HIV is expected to begin in Sydney later this year.

Will trial participants practice safe sex?

All trial participants will receive ongoing counselling about safe sex and drug use. Specific materials designed to support safe sex have been produced by ACON for trial participants and at a community level, a safe sex health promotion campaign that foregrounds the vaccine trial will be produced at the same time. As trial participants will be people whose behaviours place them at high risk of HIV acquisition, however, it is likely that some participants will not practice safe sex at all times.

The aim is to prevent any seroconversions in the Sydney participants if possible.

Can the experimental vaccine infect people with HIV?

It is not possible to get HIV from the experimental vaccine. It does not contain enough genetic material.

Is the experimental vaccine safe?

With any medical intervention in an experimental phase, it is impossible to give an absolute guarantee of safety. However, this experimental vaccine has already been in more than 250 people with no serious adverse effects. Minor side effects only were reported.

An idiosyncratic reaction to the vaccine is possible in an individual.

What were the side effects in previous trial of this experimental vaccine?

Side effects reported within three days of vaccination included:

Localised side effects such as pain at the injection site and swelling and redness at the injection site.

- Generalised side effects such as headache, fever, chills, pain in the joints or muscles, diarrhoea, sore throat, Back and/or neck pain, Nausea and vomiting, Difficulty sleeping, Cough, Runny nose or stuffy nose (sinus congestion), dizziness.

What are the main risks of participation in this trial?

Participants may have an allergic reaction to the experimental vaccine or experience an unanticipated serious side effect.

It is likely that about 80% of the people who receive the active experimental vaccine will test positive on some HIV tests even if they are not HIV infected. This false positive response is called a 'vaccine antibody positivity' reaction. This occurs because an immune response to the vaccine can look like the immune response to the presence of HIV infection. Other tests can easily distinguish between a vaccine reaction and actual HIV infection. More information about this effect is available in the STEP Study Information Booklet, which you can download from www.stepstudy.com.au

Does my participation in the trial affect participants' sex partner/s?

Participation in this trial does not directly affect participants' sexual partner/s in any way. Trial participants may still acquire and transmit HIV infection through unsafe sex or unsafe injecting with anyone of unknown or positive HIV status.

It is up to each participant to decide whether or not to discuss volunteering for the trial with significant others. Some people are likely to be supportive, however some people in other HIV vaccine trials have reported to researchers that they experienced discrimination, hostility or unwanted gossip based on assumptions of risk of infection due to assumed sexual practices, sexual preference or drug use.

Who is conducting the trial?

The STEP Study is a collaborative effort. In Australia it is being conducted by the National Centre in HIV Epidemiology and Clinical Research through St Vincent's Hospital, Darlinghurst. The Australian Federation of AIDS Organisations has been involved in its planning and oversight.

The experimental vaccine was developed by Merck & Co. Inc and funding for the trial is provided by Merck Sharp & Dohme (Australia) Pty. Ltd.

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