



STEP STUDY

STUDY 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
STUDY OBJECTIVE:	The STEP study is a trial of an experimental HIV vaccine. Initial human trials have shown that the vaccine is safe and produces immune responses, but it is not known whether these immune responses are effective against HIV. People who are at high risk of HIV will be enrolled in the STEP study to test how the vaccine works if a vaccinated trial participant subsequently exposes him or herself to HIV.
STUDY DESIGN:	This is a multicentre, double-blinded, placebo-controlled clinical trial. Volunteers will be randomised 1:1, vaccine to placebo. Volunteers will receive three 1mL intramuscular injections of the vaccine or the placebo at day 1, week 4 and 26. Clinical and laboratory follow-up, HIV-1 testing, and/or immunogenicity follow-up visits will be performed up to 5 years following the first injection.
IS THE STUDY OPEN TO PATIENT ENROLLMENT:	<p>No. The study will be open to enrolment in March 2006.</p> <p>We are seeking healthy HIV-negative volunteers, between the ages of 18 and 45 years, who fulfil at least one of the following criteria :</p> <p>Female:</p> <ul style="list-style-type: none"> • HIV positive regular male sexual partner OR • Any previous use of (non-occupational post-exposure prophylaxis) NPEP. <p>Male:</p> <ul style="list-style-type: none"> • HIV positive regular sexual partner OR • Receptive UAI with casual partner in the past 6 months OR • Reported or diagnosed anal STI (gonorrhoea/chlamydia/warts) in the past 12 months OR • Any previous use of NPEP. <p>Transgendered:</p> <ul style="list-style-type: none"> • Any previous use of NPEP OR • Assessment on an individual basis, with close reference to male criteria.

	Please see the website www.stepstudy.com.au for further details.
ENROLLMENT TARGET:	The target is 3,000 volunteers worldwide; 100 of these volunteers will come from St. Vincent's Hospital, Sydney.
STUDY COMPLETION DATE:	January 2010
STUDY DRUGS:	The Study Vaccine is called Trivalent Merck Adenovirus 5, which is derived from an adenovirus subtype 5. Adenovirus is a type of common cold virus, that is weakened in the vaccine construct so that it does not cause colds or sore throats. To make the vaccine, three synthetic HIV genes were inserted into the weakened adenovirus. The vaccine "teaches" the immune system to recognise these fragments of artificial HIV and to mount a response against them. There is no actual HIV or infectious parts of HIV in the vaccine, and it is not possible to become infected with HIV by being vaccinated
SPONSOR:	Merck Sharpe and Dohme Australia, Pty Ltd
COLLABORATOR SITES:	St Vincent's Hospital, Sydney. 21 sites in USA, Canada, Dominican Republic, Peru, Haiti and Puerto Rico.
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