

# INTERNATIONAL AIDS VACCINE INITIATIVE



## Studies in progress:

**A randomized, placebo-controlled, dosage-escalating phase I double-blinded study to evaluate the safety and immunogenicity of an MVA HIV-1 multigenic subtype C vaccine in HIV-uninfected, healthy volunteers**

## Background:

In view of the existing burden of Human Immuno Deficiency Virus (HIV) infection with its medical, social and economic dimensions, it was decided that efforts should be undertaken to test a vaccine against HIV as per the joint declaration by the National AIDS Control Organization (NACO), ICMR and the International AIDS Vaccine Initiative. For this purpose, a phase I trial of a multigenic vaccine against HIV-1 subtype C using Modified Vaccinia Ankara as the vector has been initiated.

## Aims:

To determine the safety and tolerability of three injections of the vaccine or placebo in two dose levels.

To determine the immunogenicity of this vaccine by measuring HIV-1 specific T- cell responses quantified by ELISPOT INF- $\gamma$  and serum binding antibody responses to HIV measured by ELISA.

## Methods:

A total of 32 volunteers will be enrolled in two groups and followed up for a total of 18 months as per the schedule given below:

Group	Sample size Vaccine/Placebo	Investigational product		
		Month 0	Month 1	Month 6
A	12 /4	IM $5 \times 10^7$ pfu	IM $5 \times 10^7$ pfu	IM $5 \times 10^7$ pfu
B	12 /4	IM $2.5 \times 10^8$ pfu	IM $2.5 \times 10^8$ pfu	IM $2.5 \times 10^8$ pfu

## Results:

The trial site was renovated in March 2005 and the staff recruited for the trial has been trained in Good Clinical Practices, Good Clinical Laboratory Practices and gender issues. After the installation of the laboratory equipments, cross validation of all the laboratory procedures was completed by December 2005. Mandatory



approvals from the ethical committees, Drugs Controller General of India, Genetic Engineering Approval Committee and the Health Ministry's screening committee were obtained by end of December 2005. Community advocacy activities for recruitment of volunteers were initiated thereafter in collaboration with YRG Care Centre.

Ten volunteers have been recruited (5 females) by the end of March 2006. A total of 32 volunteers are required to be recruited into the study and the study is expected to be completed by middle of 2008 once all the recruited volunteers complete the twelve month follow up after the last injection.