

1. PHASE-I PREVENTIVE HIV VACCINE TRIAL

Ongoing studies:

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 (TBC-M4) in HIV-uninfected, healthy volunteers

Background:

In view of the existing burden of 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 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 (MVA) as the vector has been initiated.

Aims:

- To determine the safety and tolerability of three injections of the vaccine or placebo at two dose levels
- To determine the immunogenicity of this vaccine by measuring HIV-1 specific T- cell responses quantified by ELISPOT interferon-gamma (INF- γ) and serum binding antibody responses to HIV measured by ELISA

Methods:

A total of 32 volunteers were enrolled in two groups and followed up for a total of 18 months.

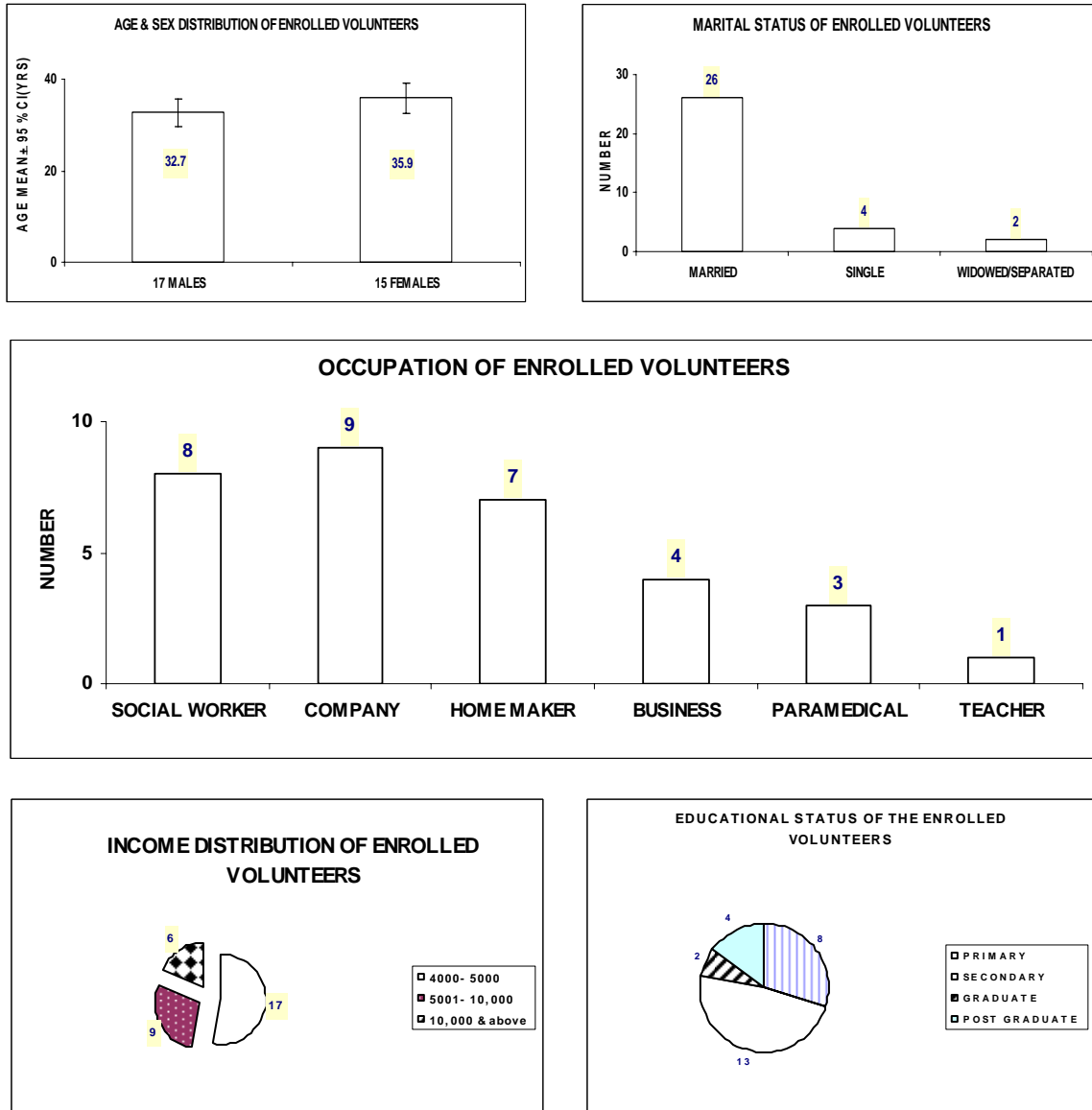
Results:

During the period under review, 32 volunteers were enrolled for the study comprising of 17 male and 15 female subjects. The demographic details of the enrolled volunteers are given in Fig.1.1-1.5. The intervention phase of the study consisting of the administration of 3 injections of the vaccine has been completed and the volunteers are in the follow up phase. A total of 457 of the scheduled

544 visits (84 %) have been completed. None of the volunteers has had any adverse or serious adverse effects related to the vaccine.

The volunteers are being followed up and the last visit is expected to be completed in February 2008.

Fig. 1.1 – 1.5: Demographic Details of volunteers



Key message: The administration of 3 injections of MVA-TBC-M4 vaccine to healthy volunteers at two dose levels appears to be safe.

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