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Phase-I prime-boost AIDS vaccine trial shows modest immune response

Results will be presented at the AIDS Vaccine 2011 conference in Bangkok in September

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CHENNAI: The final results of the Phase I prime-boost AIDS (Acquired Immune Deficiency Syndrome) vaccine trial started in February 2009 and conducted at the two sites – Tuberculosis Research Centre (TRC), Chennai, and the National AIDS Research Institute (NARI), Pune – has shown that the vaccines are safe and their ability to elicit immune response are modest.

The TRC is now called the National Institute for Research in Tuberculosis. The International AIDS Vaccine Initiative (IAVI), a non-profit organisation headquartered in New York, was a research partner.

The results will be presented at the AIDS Vaccine 2011 conference in Bangkok from September 12 to 14.

Much like the interim results presented last year in Atlanta, the final results show only a modest immune response in both the groups. Group A received ADVAX, a DNA-based vaccine, as prime and Modified Vaccinia Ankara (MVA) as boost. Group B received the MVA as a prime and boost.

"Group B was marginally superior than Group A in terms of immunological responses," said Dr. V.D. Ramanathan, the principal investigator of the Chennai trial. "We found no added advantage of DNA priming though we expected better response," said Dr. Sanjay M. Mehendale, the principal investigator of the Pune trial.

- YRG Care recruited volunteers for the trial
- No plan for more trials using TBC-M4 gene insert

All the 12 volunteers in Group A showed 100 per cent immunological response even after the third injection, and remained so after the fourth and final injection. However, in the case of Group B, the responses reached only 91.7 per cent even after the third and final injection.

"Number of volunteers showing a response alone does not mean better response," Dr. Mehendale clarified, "the magnitude, persistence and breadth of responses also matter."

Persistence (or duration of immunological response) was slightly better in the case of Group B (MVA prime and boost). But overall, the persistence was long lasting at the end of one year from the date of the last injection in both the groups.

In the case of magnitude (quantity of response), the response was modest and comparable in both the groups. Similarly, in the case of breadth of response (to how many antigens the body responded), both groups showed comparable results.

Both the groups also showed modest neutralising antibody response.

If the number of volunteers who showed immune response never reached cent per cent even after the last injection, and both the groups showed comparable results on all the parameters, how right is it to say Group B is slightly superior than Group A? "Both the groups showed comparable results despite the volunteers in Group B receiving one injection less [only three injections in Group B compared to four in the case of Group A]," Dr. Ramanathan explained.

Despite the vaccines being safe and the immunological responses being modest, there is no plan to undertake further trials using TBC-M4 gene insert. "In studies that simulated large-scale manufacturing of TBC-M4 gene insert, the MVA vector was identified as genetically unstable," explained Dr. Rajat Goyal, country director of IAVI, New Delhi. "Similar observations have been reported from several groups working on pox-based vector in the field. Several efforts for several strategies have not been successful in stabilising the vector."

YRG Care, Chennai, recruited volunteers for the TRC arm of the trial. Dr. Sunil Solomon, Director of YRG Care, said last year that recruiting volunteers was easier for the prime-boost trial compared with the first trial in TRC. This, she said, was due to more literacy in the community that the YRG was working with and the experience of the earlier trial at TRC.