

## Abstract

IAVI-006 was the first large randomised, double-blinded, placebo-controlled Phase I clinical trial to systematically investigate the prime-boost strategy for induction of HIV-1 specific CD8+ cytotoxic T-lymphocytes (CTL) in a factorial trial design using (i) priming with 0.5 mg or 2 mg of pTHr.HIVA DNA vaccine, followed by (ii) two booster vaccinations with  $5 \times 10^7$  MVA.HIVA at weeks 8 and 12 (early boost) or weeks 20 and 24 (late boost). This study set the basis for later clinical trials and demonstrated the safety of these candidate HIV vaccines. The safety and immunogenicity results are presented and the lessons derived from this clinical trial are discussed.