

Poster presentation

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## Do circulating HIV vaccine plasmids contribute to immunogenicity in humans?

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### Background

We conduct a phase 1 clinical trial where forty healthy volunteers are immunized with multigene, multiclade HIV DNA plasmids encoding nine different proteins of HIV-1 subtypes.

### Materials and methods

Total nucleic acid was extracted from plasma or sera. A nested PCR was performed using specific primers designed for the vaccine plasmids and HIV-1 DNA PCR directed against HIV genes not present in the vaccine.

### Results

Two months after the third immunization, an HIV RNA quantitative PCR was performed to confirm the non-infected status of the participants. In half of the vaccines, in total receiving 3–12 mg plasmid DNA, we noted reactions of plasmid DNA or values corresponding to 20–1200 HIV RNA copies in the Roche Amplicor assay. Env and/or gag encoding plasmids were detected in the plasma or serum of the vaccines, but no HIV. A PCR for HIV protease (the protease gene is not included in the vaccine) was negative in all cases. Antigen and antibody assays have confirmed that the individuals were not infected. The study is still blinded, but a total of over 90% have responded very well by T-cell assays.

### Conclusion

HIV vaccine plasmids given id or im were identified as late as two months after immunization. A relation between immunogenicity and circulating vaccine plasmids will be sought. DNA plasmids may give positive signals in a standard HIV RNA quantitative assay.