

Poster presentation

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## PI9-48. Induction of Ad5 neutralizing antibodies in placebo recipients during the Step Trial is not associated with risk of HIV infection

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### Background

Vaccinees in the Step Trial who were Ad5 seropositive at baseline had a trend toward increased HIV infection [2.3-fold increased incidence (CI:1.2–4.3)] (Lancet, 2008; 372(9653): 1881–93). To further explore the relationship between HIV and Ad5, we investigated evidence of incident Ad5 infection and whether HIV infection was associated with increases in Ad5 neutralizing antibody (nAb) titer in the absence of vaccination.

### Methods

Sera were assayed using the Merck Ad5 nAb assay: positive titer range 18 – 4,608. We assessed incident Ad5 infection by measuring nAb titers at 52 weeks for 208 placebo recipients who were seronegative (titer<18) at enrolment. We next assessed the association between increases in Ad5 titer (which may suggest recent Ad5 infection) and incident HIV among placebo recipients. Ad5 titer was measured at the last pre-infection visit for 33 incident HIV cases (both Ad5 seronegative and seropositive at enrolment) and at the corresponding visit for 130 matched controls; hazard ratios used the difference between Ad5 titer at enrolment and this later time point.

### Results

At 52 weeks following enrolment, we detected low positive Ad5 nAb titers in 4% (8/208) of seronegative enrollees in the placebo group; titers ranged from 19–41,

(median 23.5). We next assessed whether serologic evidence of Ad5 infection occurred at a higher rate in subjects who acquired HIV infection. Ad5 nAb titers increased in 21% of cases compared to 31% in controls [hazard ratio: 0.792 (p = 0.665)].

### Conclusion

The low incidence and magnitude of Ad5 nAb titer increases in the placebo group suggest that Ad5 infections occurred rarely, if at all, among study participants. In addition, there was no evidence of an association between HIV infection and increases in Ad5 titers in participants. Thus, post-enrolment Ad5 infection is not a predisposing factor for HIV acquisition in the placebo group of the Step Trial.