Retrovirology

BioMed Central

Poster presentation

P14-06. Phase 1 safety and immunogenicity randomised controlled trial of a vaginal gp140 vaccine

DJ Lewis[1,4], CJ Lacey*[2], S Jeffs[3], T Cole[4], C Fraser[4], R Wiggins[2], M Woodrow[4], A Cope[4], C Cai[2], E Giemza[4], A Mahmhoud[4], D Katinger[5], M Cranage[4] and R Shattock[4]

Address: [1]St George's, London, UK, [2]Hull York Medical School, University of York, UK, York, UK, [3]Imperial College, London, UK, [4]St George's, London, UK and [5]Polymun Scientific, Vienna, Austria

* Corresponding author

from AIDS Vaccine 2009
Paris, France. 19–22 October 2009

Published: 22 October 2009

Retrovirology 2009, **6**(Suppl 3):P194 doi:10.1186/1742-4690-6-S3-P194

This abstract is available from: http://www.retrovirology.com/content/6/S3/P194

Background

We wish to determine the optimal vaccination strategies for invoking genital tract mucosal immune responses that might protect against heterosexual HIV-1 transmission. We therefore conducted a phase 1 trial to determine whether vaginal immunisation with an HIV-1 envelope protein could produce genital tract and systemic immune responses.

Methods

We designed, expressed, and produced under GMP a trimeric gp140 from a clade C isolate, 96ZM651.8. A phase 1 trial to establish safety and immunogenicity was conducted. 100 μg of ZM96gp140 was mixed with 3 ml of a 0.92% Carbopol® 974P NF polymer gel and delivered intravaginally 9 times during a single menstrual cycle, with a 2:1 randomisation of active to placebo. We measured vaginal, cervical, and systemic IgG and IgA responses and systemic IFN-gamma ELISpot responses, as well as safety parameters, with a three month follow up design.

Results

The first female subject was studied with open-label active immunisation. A total of 22 subjects completed the trial. There were no serious adverse events (AEs). A variety of non-serious AEs were recorded. Apart from the first subject who produced a weak mucosal IgA response to the trimeric gp140, no other subjects developed anti-ZM96gp140 responses and none had detectable gp140-specific, IFN-gamma-secreting peripheral T cells. The treatment allocations remain blinded at the present time.

Conclusion

We have established the feasibility of conducting phase 1 trials focussing on the measurement of genital tract responses to mucosal immunisation. We did not find evidence that suggests that vaginal immunisation with an HIV envelope protein alone can induce robust genital tract or systemic anti-HIV responses. Future work will focus on alternative strategies of systemic/mucosal priming and boosting to determine the optimal immunisation regimes which can produce robust genital tract and systemic anti-HIV immune responses.