Stable lyophilised gel vehicles for vaginal administration of recombinant C-clade HIV-1 trimeric CN54gp140

Donnelly, L., Curran, R., Morrow, R., Kett, V., Andrews, G., Malcolm, K., ... Shattock, R. J. (2009). Stable lyophilised gel vehicles for vaginal administration of recombinant C-clade HIV-1 trimeric CN54gp140. Retrovirology, 6(S3), 156. DOI: 0.1186/1742-4690-6-S3-P156

Published in:
Retrovirology

Retrovirology

BioMed Central

Poster presentation

P11-11. Stable lyophilised gel vehicles for vaginal administration of recombinant C-clade HIV-1 trimeric CN54gp140

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

Published: 22 October 2009

Retrovirology 2009, **6**(Suppl 3):P156 doi:10.1186/1742-4690-6-S3-P156

This abstract is available from: http://www.retrovirology.com/content/6/S3/P156

Background

With an effective vaccine being sought for the prevention of HIV transmission, current focus is upon a mucosal vaccine strategy providing protection at the viral point of entry. The full potential of these vaccines can only be realised with the development of successful delivery systems which are also capable of providing an environment conducive to antigen stability. Previously, rheologically structured vehicles (RSVs) were formulated to include the recombinant C-clade HIV-1 envelope protein CN54gp140, and intra-vaginal immunisation in rabbits induced significant systemic IgG and specific IgG and IgA in genital tract secretions. However, CN54gp140 stability within these aqueous formulations remains a concern. Here we investigate the formulation of CN54gp140 within modified lyophilised RSV matrices as a means of providing enhanced protein stabilisation.

Methods

RSV formulations were prepared comprising mucoadhesive (polycarbophil, sodium carboxymethylcellulose) and vaginal fluid absorbing (polyvinylpyrrolidine) components. Using rheological analyses in combination with dispensing studies, formulations having appropriate flow properties were chosen for lyophilisation. *In vitro* release testing of the lyophilised CN54gp140 formulations were investigated in PBST, and following prolonged storage at 37°C the antigenicity of CN54gp140 from the lyophilised RSVs were analysed by ELISA. The antigen CN54gp140 stability profiles of these formulations were compared to the original aqueous RSV.

Results

CN54gp140 was found to be uniformly distributed within the lyophilised products and exhibited a sustained release profile over an 8 hour period during which the lyophilised 'tablet' underwent complete dissolution in the surrounding media. While recovery of CN54gp140 from the aqueous RSV diminished over 9 days, lyophilisation showed no loss in CN54gp140 antigenicity over 67 days storage.

Conclusion

Formulation of CN54gp140 within a lyophilised gel matrix is shown to have a stabilising effect on the antigen while preserving its sustained release capacity. Such a mucosal vaccine delivery system may offer numerous advantages including ease of use, long-term stability and cold chain avoidance.