Evaluation of Immunogenicity and Safety of Polymer Based Nasal Vaccine

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1. To study the effect of particle size and surface charge on systemic and mucosal immune response.
2. To check the ability of chitosan derivatives as mucosa-adsorptive polymer.
3. To investigate the stability of recombinant HbsAg within coated and uncoated PLGA Nanoparticles.
4. To develop a needle-free vaccination i.e., Mucosal administration (Nasal route).
5. To evaluate Systemic and Mucosal immune responses.

**CHARACTERIZATION OF NANOPARTICLES**

- Estimation of HBsAg content in PLGA Nanoparticles
- Entrapment efficiency (%)
- Particle Uptake studies

**MUCOSAL IMMUNE RESPONSE**

- Systemic Immune Response (IgG LEVELS)
  - The concentration of anti-HbsAg antibody by solid phase ELISA
- Mucosal Immune Response (IgA LEVELS)
  - The concentration of anti-HbsAg antibody by solid phase ELISA

**FLUORESCENCE MICROSCOPY**

- Fluorescence microscopy images showing the uptake of FITC-BSA-loaded nanoparticles in NALT.

**ADSORPTION OF MUCIN ON NANOPARTICLES**

- Mucin adsorption mg/mg of particles

**EVALUATION OF TOXICITY BY CILIARY BEAT FREQUENCY**

- Ciliary beat frequency after exposure to 0.5 mg/ml HBsAg-loaded nanoparticles as a measure for nasal cilia toxicity.

**IN VITRO RELEASE STUDIES**

- Graph showing % cumulative HBsAg release from coated and uncoated PLGA nanoparticles in PBS (pH 7.4).

**SYSTEMIC IMMUNE RESPONSE (IgG LEVELS)**

- Graph showing anti-HbsAg IgG titer in serum in different groups immunized with native HbsAg, alum-HbsAg and developed formulations.

**CONCLUSION**

- Particle size and surface charge have major impact on mucosal immunity. The extent of the absorption of the antigen encapsulated into the particles was dependent on the size of the particles, being more important for the Nanoparticles than for the Microparticles.

- Choice for the practical development of Particulate vaccine for mucosal immunization.