Evaluation of long-term stability and biological activity of emulsion-based nanoadjuvants

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Statement of the problem In spite of the work done by many research groups, there is still a shortage of safe and effective vaccine adjuvants on the market, especially those specialized for mucosal administration. Currently used adjuvants do not meet the needs to formulate the robust and efficacious vaccines. In response to these needs, we propose a new class of adjuvants, named as nanoadjuvants, composed of well-characterized and safe ingredients, based on an oil-in-water emulsion. **Methodology** The emulsion has been characterized physicochemically and biologically using several methods. The stability of the emulsion during long-term storage (up to 12 months in 4°C, RT or 37°C) and the interaction of the emulsion with model antigen (OVA) were investigated. The cytotoxicity of the emulsion and production of proinflammatory cytokines were carefully evaluated. **Findings** Several nanoadjuvants are stable up to 12 months in RT and are undamaged by sterilization (120°C, 20 min). Various nanoadjuvants can be obtained by changing the composition and amounts of ingredients. Droplet size and zeta potential of nanoadjuvants influence both physical and biological properties such as bioadhesiveness, cytotoxicity and the capacity of antigen incorporation. **Conclusion & Significance** We prepared and characterized new emulsion-based formulations as a potential new class of adjuvants (nanoadjuvants) for both parenteral and mucosal vaccine administration. Our formulation may greatly contribute to development of novel vaccines.

Publications

1. Ziaco, M., Górska, S., Traboni, S., Razim, A., Casillo, A., Iadonisi, A., Gamian, A., Corsaro, M.M. & Bedini, E. (2017). Development of Clickable Monophosphoryl Lipid A Derivatives toward Semisynthetic Conjugates with Tumor-Associated Carbohydrate Antigens. *Journal of Medicinal Chemistry*.
2. Górska, S., Dylus, E., Rudawska, A., Brzozowska, E., Srutkova, D., Schwarzer, M., Razim, A., Kozakova H. & Gamian, A. (2016). Immunoreactive proteins of Bifidobacterium longum ssp. longum CCM 7952 and Bifidobacterium longum ssp. longum CCDM 372 Identified by gnotobiotic mono-colonized mice sera, immune rabbit sera and non-immune human sera. *Frontiers in microbiology*, *7*.
3. Mehlich, A., Gorska, S., Gamian, A., & Myc, A. (2015). Selected aspects of Clostridium difficile infection. *Postepy higieny i medycyny doswiadczalnej*, *69*, 598-611.



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