

## VAC\_15 - Nasal COVID-19 vaccine

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**Introduction:** The nasal vaccine formulation was developed to induce an early protection against the SARS-CoV-2 infection, to be initiated at the entry of the virus in the airway mucosa.

**Objective:** The formulation was able to induce an efficient immunity to the virus that included neutralizing lung mucosal antibodies without inducing adverse effects such as exaggerated lung inflammation.

**Methodology:** The nanoformulation includes the SARS-CoV-2 Spike (S) protein and an adjuvant, using a liposomal delivery system to reach the immune system. Stability tests and nano-characterization of the formulation were performed. The COVID-19 model was performed in transgenic mice carrying the human ACE2 receptor, who were vaccinated via intra-nasal or subcutaneously and then infected with different SARS-CoV-2 variants.

**Results:** Vaccinated animals were protected against the Wuhan, gamma and delta variants of SARS-CoV-2, with no presence of virus in the lung 2, 4 and 6 days after infection. The nasal vaccine was more effective than the subcutaneous administration, inducing higher titers of neutralizing antibodies, such as IgA, able to neutralize the virus in the lung and in the blood. *In vitro* toxicity testes of the vaccine formulation in different cells types (including human lung cells) showed no cytotoxicity.

**Conclusion:** The results so far indicate that the nasal vaccine is 100% efficient in preventing COVID-19 and the potential use of this formulation for humans will depend on clinical trials that are the next goal of the present project.

**Keywords:** Nasal vaccine COVID-19