NECTM7
Stockholm May 2-4 2018

A single center randomized open-label clinical trial to assess the immunogenicity and safety of a one visit dosing regimen of intradermal Purified Chicken Embryo Cell Rabies Vaccine in adults with and without topical imiquimod.

Benjamin Damanet[2], Petra Andries[2], Katrien DeKoninck[2], Emmanuel Bottieau[3], Patrick Soentjens[1]

[1]*Institute of Tropical Medicine, Antwerp*
[2]*Center for Infectious diseases, Queen Astrid Military Hospital, Brussels*
[3]*Dept of Clinical Sciences, Institute of Tropical Medicine, Antwerp*

Background
More convenient seven-day pre-exposure vaccination schedules have recently shown non-inferiority to conventional 3 to 4-week schedules and are now advised by the WHO SAGE group (1-3). Recent data demonstrated that 83% of subjects having received such a single visit primary vaccination with intradermal micro-injections (0.1 ml) had a sufficient initial antibody response of ≥ 0.5 IU/ml after 14 days (4).

Objective
To investigate the additional effect of the topical pre-administration of imiquimod on the antibody response on day 7 after a single visit primary intradermal vaccination.

Method
Naïve Belgian soldiers (N=268) are being vaccinated with a double intradermal vaccination injection (2 x 0.1 ml) during one single visit, using the Purified Chicken Embryo Cell Vaccine. Within this study (EudraCT 2017-002953-12), subjects are randomized for the topical treatment with imiquimod versus placebo cream. The primary endpoint is the antibody response on day 7 after booster vaccination at 1 year after primary vaccination.

Here, we report on one of the secondary endpoints: the comparisons of the antibody response 7 days after the primary vaccination in both groups (exposed to topical imiquimod or not). A titer ≥ 0.5 IU/ml (as measured by Rabies Fluorescent Focus Inhibition Test) is considered to be boostable lifelong.

Results
Demographic data of the 268 enrolled participants as well as their serological responses after single visit primary intradermal vaccination, either with imiquimod pre-administration or not will be available in April 2018, and will be presented during the congress.

Conclusions
We hypothesize in this randomized clinical trial, that pretreatment of imiquimod will improve the early antibody response of primary intradermal rabies vaccination, compared to intradermal injections alone.