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Titel des Beitrags: Safety and immunogenicity of modified vaccinia Ankara as a smallpox vaccine in people with atopic dermatitis.

Abstract: Following vaccination with traditional smallpox vaccines or after exposure to vaccinated individuals, subjects with atopic dermatitis (AD) can develop eczema vaccinatum, a severe disease with disseminated eruption of pustular contagious lesions. Alternative smallpox vaccines with an improved safety profile would address this unmet medical need. An open-label controlled Phase I clinical trial was conducted to investigate the safety and immunogenicity of modified vaccinia Ankara (MVA) in 15 healthy subjects compared to 45 subjects with either mild allergic rhinitis, a history of AD or presenting with mild active AD. MVA was given (Week 0 and 4) by a subcutaneous injection during a 28-week observation period. No serious adverse event was reported and vaccinations with MVA did not lead to any clinically relevant skin reactions in AD subjects. Unsolicited administration site reactions did not show any trends compared to the healthy subject group. The majority of adverse reactions were mild to moderate, and all reactions were transient and resolved without intervention. The majority of vaccinees had seroconverted by ELISA (80-93%) and PRNT (69-79%) already two weeks after the first vaccination, increasing to 100% after the second immunization, with peak GMT above
1000 and 145 for ELISA and PRNT, respectively. MVA was equally well tolerated and immunogenic in all enrolled subjects with mild to moderate pain and redness at the injection site being the most frequent adverse reactions. There were no differences in the safety or immunogenicity profile of MVA in healthy subjects or those with AD or allergic rhinitis. The study has confirmed MVA as a promising smallpox vaccine candidate and demonstrated in a small study population that the vaccine has a similar safety and immunogenicity profile in healthy subjects and people with active AD. NCT00189917.