OMICS Group Conferences
Accelerating Scientific Discovery

3rd International Conference on
Vaccines & Vaccination
July 29-31, 2013 Embassy Suites Las Vegas, NV, USA

Efficacy study of a therapeutic human papillomavirus (type-16) vaccine (a recombinant HPV16 L2E6E7 fusion protein) in mouse and macaque experiments

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Purpose: The study purpose is to evaluate a therapeutic human papillomavirus (type-16) vaccine (a recombinant HPV 16-L2E6E7 fusion protein) the dose-response, immunization procedure in mouse model and specific E6 INF-r and specific E7INF-r responses in monkeys.

Methods: Mouse model was C57 BL/6 mice. Each group in mouse included 10 or 20 C57 BL/6 mice. The tumor model used TC-1 tumor cells. The HPV16 L2E6E7 vaccine groups were treated using the following dosage: 15 μg/ml, 30 μg/ml, 60 μg/ml, 120 μg/ml, 240 μg/ml, plus a control group. Based on results from the dose-response experiment, 60 μg/ml and 120 μg/ml dosage groups were used for the following regimens: days 0 and 7 (0-7), days 0 and 15 (0-15), days 0, 7, and 15 (0-7-15), and a control group (also 0-7-15). Macaque was detected the specific E6 INF-r and specific E7 INF-r used ELISPOT; each group included 3 macaques and different regiments with 0-7-14-28 weeks schedule.

Results: Upon challenge with 10,000 TC-1 cells, mice developed palpable, rapidly growing tumors within 9-14 days. These tumors became lethal to the mice within 21-28 days. HPV16 L2E6E7 vaccine at a dose of 120 μg/ml with 0-7-15 procedure protected the majority of mice against tumor outgrowth (protective efficacy 85%). For E6 peptide specific IFN-r, 2 out of 3 macaques showed the high level insignificance; and E7 peptide specific IFN-r only 1 out of 3 macaques showed the high level in significance.

Conclusion: A therapeutic HPV16 L2E6E7 vaccine at a dosage of 120 μg/ml with 0-7-15 procedure protected the 85% of mice against tumor outgrowth and can induce E6 peptide specific IFN-r in macaque.

Keywords: Human papillomavirus-16, fusion protein, therapeutic vaccine, efficacy.

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