

Evaluating Immunogenicity and Safety Effect on Combined Immune Effect of EV71 Inactivated Vaccine and HepB、MPSV-A、MR、JE-L : A Multi-center Randomized Controlled Trial

Registered classification: prevention of biological products

Clinical stage: stage IV

Program number: EV71-2017-03

Version date: 05 01 2018

Bidding unit:

China Biotechnology Limited by Share Ltd

Wuhan biological products research institute limited liability company

Research unit:

Shandong Center for Disease Control and Prevention

Hunan Center for Disease Control and Prevention

Shaanxi Center for Disease Control and Prevention

Shanxi Center for Disease Control and Prevention

Statistical analyses

The quantitative index lists the standard deviation, the median, the maximum and the minimum, and the qualitative index or the grade index list the frequency distribution table. The antibody titers of immunogenicity index should be represented by geometric mean, median, maximum and minimum value and 95% confidence interval. The antibody titer should be analyzed by logarithmic transformation.

A list of the total population, susceptible and non susceptible seroconversion rate and 95% confidence interval, and calculation (test group and control group) rate difference and 95% confidence interval, non-inferiority test; the test group and the control group between the antibody geometric mean (GMT/GMC) compared with the t test after logarithmic transformation P, with less than 0.05 as there were statistically significant differences in the standard.

Arms

Experimental: Combination inoculation group Group I : HepB:3+EV71 Group II : MPSV-A:1+EV71 Group III: MR+EV71 Group IV: JE-L+EV71 Inoculation vaccine made by different techniques(EV71 vaccine 0.5ml per dose, Wuhan Biological Products Co., Ltd., Wuhan, Hubei Province, China; 10 μ g HepB 0.5ml per dose, Wuhan Biological Products Co., Ltd., Wuhan, Hubei Province, China; 30ug MPSV-A 0.5ml per dose, Wuhan Biological Products Co., Ltd., Wuhan, Hubei Province, China; MR 0.5ml per dose, Beijing Biological Products Co., Ltd., Beijing, China; JE-

L 0.5ml per dose, Chengdu Biological Products Co., Ltd., Chengdu, Sichuan Province, China) were given intramuscularly in the deltoid region to participants.

Active Comparator: Separate inoculation control group Group I : HepB:3 Group II : MPSV-A:1 Group III: MR Group IV: JE-L Inoculation vaccine made by different techniques (EV71 vaccine 0.5ml per dose, Wuhan Biological Products Co., Ltd., Wuhan, Hubei Province, China; 10 μ g HepB 0.5ml per dose, Wuhan Biological Products Co., Ltd., Wuhan, Hubei Province, China; 30ug MPSV-A 0.5ml per dose, Wuhan Biological Products Co., Ltd., Wuhan, Hubei Province, China; MR 0.5ml per dose, Beijing Biological Products Co., Ltd., Beijing, China; JE-L 0.5ml per dose, Chengdu Biological Products Co., Ltd., Chengdu, Sichuan Province, China) were given intramuscularly in the deltoid region to participants.

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Assigned Interventions

Biological/Vaccine: Inoculation vaccine EV71 vaccine 0.5ml per dose, Wuhan

Biological Products Co., Ltd., Wuhan, Hubei Province, China 10µg HepB 0.5ml per dose, Wuhan Biological Products Co., Ltd., Wuhan, Hubei Province, China 30ug MPSV-A 0.5ml per dose, Wuhan Biological Products Co., Ltd., Wuhan, Hubei Province, China MR 0.5ml per dose, Beijing Biological Products Co., Ltd., Beijing, China JE-L 0.5ml per dose, Chengdu Biological Products Co., Ltd., Chengdu, Sichuan Province, China

Outcome Measures

Primary Outcome Measure:

1. Statistical analysis of immunogenicity 1. Serum antibody positive rate, antibody 4 times growth rate, antibody positive rate (4 times increase) rate and confidence interval, and non-inferiority test of antibody positive rate 2. Antibody titer / concentration distribution before and after immunization.

2. Secondary Outcome Measure:

2. Population characteristics of the subjects 1. Demographic equilibrium and basic statistical indicators 2. the number of entering, completing, falling off, deviating from the scheme and the reasons
3. Statistical analysis of Clinical safety
 1. the occurrence of undesirable events, non-collection events, falling off and serious adverse events 2. the occurrence of adverse events at different severity levels 3. the occurrence of symptoms of adverse reactions at different severity levels 4. Special attention should be given to the cases of termination or withdrawal due to adverse events and serious or serious adverse events, and

lists detailed account of falling off, termination / exit, deviation / violation,
adverse events and serious adverse events.