Progress on the booster study of inactivated COVID-19 vaccine

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Phase I/II Clinical Study Protocol

Phase I/II: To evaluate vaccine safety in different populations, different doses, and different immunization schedules, and to explore immunogenicity

- Total subjects: 480 subjects in PhI; 1648 subjects in PhII
- Immunization schedule: 0, 28, 56 days
- Age group: 3-5 years old, 6-12 years old, 13-17 years old, 18-56 years old, 60 years old
- Immunogenicity: Neutralizing antibodies 28 days after full course vaccination
- Safety: regular phone calls, follow-up visits, safety observations
- Immune persistence: 90, 180 and 360 days after full course vaccination
The incidence of adverse reactions after the third dose (0%, 5%) was lower than that of the second dose (6.67%, 15%) in the low and middle dose groups.

There was no difference in the incidence of adverse reactions after the third dose (11.67%) and the second dose (15%) in the high-dose group.
90 days after the full course of immunization, there was no difference in the level of neutralizing antibodies between 2 doses and 3 doses.

90 days after the full immunization, the antibody level did not decrease significantly, and 180 days after the immunization, there was a decline trend.

The level of neutralizing antibodies after 3 doses of vaccination is superior than that of 2 doses.
In the 13-17-year-old group, the neutralizing antibody level after 3 doses was significantly higher than that of 2 doses, and the antibody level increases with the increase of doses;

- The antibody GMT at 90 days after the full immunization was slightly lower than that at 28 days, but it still maintained a high level.
Phase III clinical study: booster immunization

- Booster vaccination:
  - Maintain the original protocol, BIBP group, WIBP group and placebo group were vaccinated with booster vaccines according to the original grouping.
  - The 3rd dose was administered 6 months after the 2nd dose, and 9,000 people were vaccinated.

- Immunization schedule: 0, 21(+7) days, 6M
- Age group: ≥18 years
Local adverse reactions after 3rd dose were mainly pain, with an incidence of 21%; Not significantly different from the first two doses (19%).

Systemic adverse reactions after 3rd dose were mainly headache, fatigue and muscle pain, which were lower than the incidence of corresponding symptoms after the first two doses.
Changes over time in antibody level after booster immunization

Comparison of neutralizing antibody titers against different strains between 2 and 3 doses

- 6M after 2 doses, 14 days after 1 dose of booster immunization, neutralizing antibodies increased rapidly, 10 fold antibody increase 28 days after booster immunization
- Seroconversion rate was 100%
Both 2 doses and 3 doses can produce cross-protection effects against Beta strain and Delta strain;

In comparison with the neutralizing antibody titer against the Vaccine strain, there is relatively small decrease in the antibody titer against Delta strain, and the magnitude of decrease against Delta strain was less than that of Beta strain, but still, it showed a protective effect.
Thank you!