Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: Immunogenicity and safety of 2009 pandemic H1N1 vaccine in 6-35 months old children
Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):
Authors/sponsors: Dr Yong Zou / Sinovac Biotech Ltd.
Study Design: Phase II randomized, blinded controlled clinical trial
Vaccine: H1N1 Strain: A/California/07/2009 Manufacturer: Sinovac Biotech LTD
Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): Inactivated split eggs – derived vaccine. Seasonal influenza vaccine was used as control
Adjuvant: Al(OH)3
Delivery system/site: IM injection
Doses (antigen and adjuvant): 7.5 µg, 15 µg of HA per dose. Two doses at day 0 and 21

Study population: 300 children
Age range: 6-35 months Health status: Healthy
Specific inclusion criteria:
Specific exclusion criteria:

Clinical Endpoints Assessed
Safety assessments:
Participants with adverse reactions after vaccination
Total 38 (30.6%) 32 (26.0%) 23 (36.5%)
Mild 20 (16.1%) 12 (9.8%) 10 (15.9%)
Moderate 17 (13.7%) 16 (13.0%) 11 (17.5%)
Severe 1 (0.8%) 4 (3.3%) 2 (3.2%)

Immunogenicity assessments: Laboratory tests performed by National Institute for the Control of Pharmaceutica and Biological Products (NICPBP). Blood for antibody testing was collected on days: 0, 21, 42

Immunooassay type:
HI Neutralization (type of neutralization assay):
Others:

Results:
Safety: Vaccine shows good safety in 6-35 months old children

Immunogenicity:
GMTs
GMT Ratios (post:pre)
Fold increase in HI after 1 and 2 doses:
1 2
6.8 33.2 15µg
5.9 28.1 7.5µg"%

Per cent responding (4 fold or greater rise and definition for reporting):
HI≥4 after 1 and 2 doses:
1 2
58% 96% 15µg
48% 92% 7.5µg"%

Per cent responders at specified titer:
HI≥40 after one and two doses:
1 2
<table>
<thead>
<tr>
<th>Percentage</th>
<th>Value</th>
<th>Dose</th>
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<tbody>
<tr>
<td>60%</td>
<td>95%</td>
<td>15µg</td>
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<tr>
<td>49%</td>
<td>92%</td>
<td>7.5µg</td>
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**Others:**
Conclusion: Two doses of PANFLU.1 (7.5µg per dose) were immunogenic to 6-35 months old children. Very low cross-reactivity existed between 2009 pandemic and seasonal H1N1 virus.

**Status of trial (ongoing/completed):** Completed in 2009-2010