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Assessment of the immunogenicity and safety of the Northern Hemisphere 2009/2010-season influenza vaccine in children aged 6 to 35 months in comparison to a commercially available influenza vaccine

Submission date 23/09/2009	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 20/10/2009	**Overall study status** Completed	
Last Edited 20/10/2009	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
TG0826INF

Study information

Scientific Title
Assessment of the immunogenicity and safety of the Northern Hemisphere 2009/2010-season influenza vaccine in children aged 6 to 35 months in comparison to a commercially available influenza vaccine: an observer-blind, randomised, controlled, safety/immunogenicity study

Study objectives
The Northern Hemisphere 2009/2010-season virosomal influenza vaccine is as immunogenic as the comparator vaccine.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Medical Ethics Committee in China approved on the 11th September 2009 (ref: IRB No. 00001594)

Study design
Observer-blind randomised controlled safety/immunogenicity study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Influenza

Interventions
Biological: two doses of trivalent virosomal adjuvanted influenza vaccine (Inflexal® V) or control vaccine. Total duration of follow-up: approximately 1.5 months.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
2009/2010-season virosomal influenza vaccine (Inflexal® V)

Primary outcome(s)
Immunogenicity, assessed by haemagglutination inhibition test; blood to be collected at baseline and approximately three weeks after second dose administration.

Key secondary outcome(s))
Safety, assessed at baseline and at three to four weeks after each vaccination, including a four-day adverse event questionnaire, soliciting a set of local and systemic adverse events (AEs).

Completion date

30/04/2010

Eligibility

Key inclusion criteria
1. Healthy children (male or female) aged 6 to 35 months
2. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 months

Upper age limit
35 months

Sex
All

Key exclusion criteria
1. Previous influenza vaccination
2. Serious adverse reaction to any influenza vaccine
3. Medical treatment with immune suppressant or immune modulating drugs
4. Presentation of clinical symptoms of active infection and/or body temperature greater than or equal to 38°C

Date of first enrolment
28/09/2009

Date of final enrolment
30/04/2010

Locations

Countries of recruitment
China

Study participating centre

Guangxi Zhuang Autonomous Region CDC
Nanning, Guangxi, China
China
530028

Sponsor information

Organisation
Berna Biotech Ltd, a Crucell Company (Switzerland)

Funder(s)

Funder type
Industry

Funder Name
Berna Biotech Ltd, a Crucell Company (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration