

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/10/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/10/2009	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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).

Overall study start date

28/09/2009

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

Age group

Child

Lower age limit

6 Months

Upper age limit

35 Months

Sex

Both

Target number of participants

1239

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)

Sponsor details

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Sponsor type

Industry

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Funder(s)

Funder type

Industry

Funder Name

Berna Biotech Ltd, a Crucell Company (Switzerland)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration