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Randomised, Double-blinded, Placebo-controlled Clinical Trial of Pandemic Influenza Inactive Vaccine on Healthy Subjects

Submission date	Recruitment status	[_] Prospectively registered
25/07/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/08/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/05/2019	Infections and Infestations	

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
Nil known

IRAS number

ClinicalTrials.gov number

NCT00356798

Secondary identifying numbers
PRO-PanFlu-1001

Study information

Scientific Title
Randomised, Double-blinded, Placebo-controlled Clinical Trial of Pandemic Influenza Inactive Vaccine on Healthy Subjects

Acronym
RDPCTPIIVHS

Study objectives
An inactivated monovalent A/H5N1 (influenza A virus) whole-virion, aluminum hydroxide adjuvated influenza vaccine will be safe and immunogenic in humans.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval gained from the ethical review committee of China Japan Friendship Hospital dated on 12 December 2005 (reference: 2005NO[37]Total[99]).

Study design
A stratified, randomised, placebo-controlled and double-blind phase I clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Pandemic influenza

Interventions
The trial is divided into four dosage groups and processed from low dosage vaccine to high dosage vaccine:

1. Group A: 30 subjects will be randomly injected with vaccines among which 24 subjects will be injected with the trial vaccine (1.25 μg) antigen and the other six subjects will be randomised into a placebo group. All subjects will be observed for 30 minutes for immediate reactions. Local reactions and systemic reactions were then observed at six, 24, 48 and 72 hours. The second dose will be injected 28 days after the first dose. The dosage, injection and observation method are the same as the first one. Subjects will be followed up for 210 days. Serum will be collected before the injection and then at 14, 28, 42, 56, 210 days after injection. The serums will be tested by the Haemagglutination-Inhibition (HI) assay.

2. Group B: 72 hours after the injection of Group A, when the safety of the vaccine is confirmed, 30 subjects will be randomly injected with vaccines, among them, 24 subjects will receive the trial vaccine (2.5 μg) and the other six subjects will be receive the control. The methods of safety observation and blood collection are as same as Group A.

3. Group C: 72 hours after the injection of Group B, when the safety of vaccine is confirmed, 30 subjects will be randomly injected with the vaccine. In the same way, 24 subjects will receive the trial vaccine (5.0 μg) and the other six subjects will receive the control. The methods of safety observation and blood collection are as same as Group A.

4. Group D: 72 hours after injection for the Group C, when the safety of vaccine is confirmed, 30 subjects will be randomly injected with vaccines. Among them, 24 subjects will receive the trial vaccine (10.0 μg) and the other six subjects will receive the control. The methods of safety observation and blood collection are as same as Group A.

Trial vaccine is designed 0.5 ml per dose. The administration regimen is designed as a two dose schedule, which are given at day zero and day 28.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Influenza A virus vaccine

Primary outcome measure
To evaluate the safety of pandemic inactivated influenza vaccine by different doses.

Secondary outcome measures
To evaluate the immunogenicity of pandemic inactivated influenza vaccine by different doses.

Overall study start date
20/12/2005

Completion date
05/06/2006

Eligibility

Key inclusion criteria

1. Males and females, aged from 18 to 60 years old
2. Able to provide proof of identity to the satisfaction of the study clinician completing the enrolment process
3. Able and willing to complete the informed consent process

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
120

Total final enrolment
120

Key exclusion criteria
1. Women who are breast-feeding or planning to become pregnant during the following 210 days of study participation
2. Subjects who engage in the occupations of culturist, slaughter, sale and forwarder of any avian organisms
3. Subject has a medical history of any of the following:
a. allergic history, or allergic to any ingredient of vaccine, such as egg, egg protein etc.
b. serious adverse reactions to vaccines such as anaphylaxis, hives, respiratory difficulty, angioedema, or abdominal pain
c. autoimmune disease or immunodeficiency
d. asthma that is unstable or required emergency care, urgent care, hospitalisation or intubation during the past two years or that requires the use of oral or intravenous corticosteroids
e. diabetes mellitus (type I or II), with the exception of gestational diabetes
f. history of thyroidectomy or thyroid disease that required medication within the past 12 months
g. serious angioedema episodes within the previous three years or requiring medication in the previous two years
h. bleeding disorder diagnosed by a doctor (e.g. factor deficiency, coagulopathy, or platelet disorder requiring special precautions) or significant bruising or bleeding difficulties with Intramuscular (IM) injections or blood draws
i. malignancy that is active or treated malignancy for which there is not reasonable assurance of sustained cure or malignancy that is likely to recur during the period of study
j. seizure disorder other than febrile seizures under the age of two, seizures secondary to alcohol withdrawal more than three years ago, or a singular seizure not requiring treatment within the last three years

k. asplenia, functional asplenia or any condition resulting in the absence or removal of the spleen
l. Guillain-Barre Syndrome (GBS)
4. The abnormal result of laboratory tests as below:
a. biochemistry assaying: Alanine Aminotransferase (ALT)/Serum Glutamate Pyruvate Transaminase, Total Bilirubine (TBIL), Direct Bilirubine (DBIL), Blood Urea Nitrogen (BUN) and Creatinine (Cr)
b. Routine blood assaying, routine urine assaying
c. Hepatitis B surface Antigen (HBsAg) positive
d. pregnancy test positive
5. Subject has received any of the following substances:
a. immunosuppressive medications or cytotoxic medications or inhaled corticosteroids within the past six months (with the exception of corticosteroid nasal spray for allergic rhinitis or topical corticosteroids for an acute uncomplicated dermatitis)
b. blood products within three months prior to initial study vaccine administration
c. other study drug within 30 days prior to initial study vaccine administration
d. live attenuated vaccines within 30 days prior to initial study vaccine administration
e. medically indicated subunit or killed vaccines, e.g. pneuomococcal, or allergy treatment with antigen injections, within 14 days of study vaccine administration
f. current anti-tuberculosis prophylaxis or therapy
6. Fever before vaccination, axillary temperature 37.0°C
7. Psychiatric condition that precludes compliance with the protocol, past or present psychoses, past or present bipolar disorder requiring therapy that has not been well controlled on medication for the past two years, disorder requiring lithium, or suicidal ideation occurring within five years prior to enrolment
8. Any medical, psychiatric, social condition, occupational reason or other responsibility that, in the judgment of the investigator, is a contraindication to protocol participation or impairs a volunteer's ability to give informed consent

Date of first enrolment
20/12/2005

Date of final enrolment
05/06/2006

Locations

Countries of recruitment
China

Study participating centre
Department of Respiratory Internal
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Sponsor information

Organisation
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Sponsor type
Industry

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ROR
https://ror.org/057f25d66

Funder(s)

Funder type
Government

Funder Name
The study was funded by a grant (2005BA723B02) from Ministry of Science and Technology of the People's Republic of China.

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/09/2006	03/05/2019	Yes	No