# Clinical trial of safety (reactogenicity) and immunogenicity of needle-free jet injection of reduced-dose, intradermal, Influenza vaccine (INF) administered to more than or equal to six month- to less than 24 month-old infants and toddlers in the Dominican Republic

Submission date	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li><li>Protocol</li></ul>		
04/10/2006				
Registration date	Overall study status	Statistical analysis plan		
16/04/2007	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
09/01/2020	Infections and Infestations			

# **Plain English summary of protocol**Not provided at time of registration

# **Contact information**

Type(s)

Scientific

### Contact name

Dr Martin Friede

### Contact details

World Health Organization (WHO) 20 Avenue Appia Geneva-27 Switzerland CH-1211

# Additional identifiers

EudraCT/CTIS number

IRAS number

### ClinicalTrials.gov number

NCT00386542

### Secondary identifying numbers

RPC170; CDC-ISO-4785

# Study information

### Scientific Title

Clinical trial of safety (reactogenicity) and immunogenicity of needle-free jet injection of reduced-dose, intradermal, Influenza vaccine (INF) administered to more than or equal to six month- to less than 24 month-old infants and toddlers in the Dominican Republic

### Study objectives

Intradermal administration of a fraction (40%) of a dose of influenza vaccine with a needle-free injector induces a non-inferior immune response compared to intramuscular injection of a full dose, in infants and toddlers.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approval received from:

- 1. Dominican Republic: Local ethics committee (Consejo Nacional de Bioética en salud (CONABIOS Universidad Catolica Santo Domingo) on 27th June 2006
- 2. USA: Centres for Disease Control and prevention (CDC) Institutional Review Board on 23rd June 2006
- 3. Switzerland: World Health Organization Research Ethics Review Committee (WHO ERC) on 28th August 2006

### Study design

Clinical research, randomised controlled trial.

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

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

Influenza

### Interventions

All volunteers are bled at day of first injection and receive:

Group 1: intramuscular injection with needle 0.25 mL influenza vaccine

Group 2: intramuscular injection with needle 0.1 mL influenza vaccine

Group 3: intradermal injection jet injector 0.1 mL influenza vaccine

All volunteers are bled 28 days after first injection and receive:

Group 1: intramuscular injection with needle 0.25 mL influenza vaccine

Group 2: intramuscular injection with needle 0.1 mL influenza vaccine

Group 3: intradermal injection jet injector 0.1 mL influenza vaccine

All volunteers bled 56 days afer first injection and receive:

Groups 2 and 3 (those who received only 0.1 mL doses) receive intramuscular injection of 0.25 mL influenza vaccine.

The Principal Investigator for this trial is:

**Bruce Weniger** 

Centres for Disease Control and prevention (CDC)

1600 Clifton Road (D-26)

Atlanta, GA 30333

United States of America

Telephone: +1 404 639 8779

Email: bgw2@cdc.gov

### **Intervention Type**

Drug

### Phase

**Not Specified** 

### Drug/device/biological/vaccine name(s)

Influenza vaccine

### Primary outcome measure

Safety

### Secondary outcome measures

**Immunogenicity** 

### Overall study start date

01/10/2006

### Completion date

01/08/2007

# **Eligibility**

### Key inclusion criteria

- 1. Age from six or older to less than 24 months
- 2. Born after a full-term pregnancy of gestational age of more than or equal to 37 weeks, and a

birth weight of more than or equal to 2.5 kg

- 3. History of prior or first attendance as a patient, or as a sibling of a patient, seeking routine immunisation or other clinical care at the Hospital Infantil Robert Reid Cabral (HIRRC)
- 4. Up-to-date for routine doses of vaccines officially recommended for the participants age in the Dominican Republic
- 5. In good health

### Participant type(s)

Patient

### Age group

Child

### Lower age limit

6 Months

### Upper age limit

24 Months

### Sex

**Not Specified** 

### Target number of participants

450

### Key exclusion criteria

- 1. Have fever (by parental report or by rectal temperature greater than or equal to 38.5°C or axillary greater than or equal to 38.0°C) currently or within the past three days, or who are currently suffering from an acute or chronic infectious disease
- 2. Have had an acute or chronic infection requiring systemic antimicrobial therapy (antibiotic or antiviral) or other prescribed treatment within the past 21 days
- 3. Are malnourished, defined by weight less than two standard deviations below the median weight for their age
- 4. Are allergic to eggs, or have a history of any anaphylactic shock, asthma, urticaria, or other allergic reaction after previous vaccinations, or have allergy or hypersensitivity to any component of the study vaccine
- 5. Have ever received previously any influenza vaccine
- 6. Have received within the prior 28 days, or for whom there is the indication to receive in the next 56 days, any non-study vaccination or investigational agent outside of the study
- 7. Have a known bleeding diathesis, or any condition that may be associated with a prolonged bleeding time
- 8. Have currently any serious confirmed or suspected disease, such as metabolic, cardiac, or autoimmune disease, or diabetes
- 9. Have a history of epilepsy or a seizure disorder, or neurodevelopmental disorders such as autism
- 10. Have any condition which, in the opinion of the investigator, may interfere in the evaluation of the objectives of the study

### Date of first enrolment

01/10/2006

### Date of final enrolment

01/08/2007

# Locations

### Countries of recruitment

Dominican Republic

Switzerland

Study participating centre World Health Organization (WHO)

Geneva-27 Switzerland CH-1211

# Sponsor information

### Organisation

Centers for Disease Control and Prevention

### Sponsor details

1600 Clifton Road (D-26) Atlanta United States of America GA 30333 +1 404 639 8779 bgw2@cdc.gov

### Sponsor type

Government

### Website

http://www.cdc.gov/

### **ROR**

https://ror.org/042twtr12

# Funder(s)

# Funder type

Government

### **Funder Name**

Centers for Disease Control and Prevention

### Alternative Name(s)

United States Centers for Disease Control and Prevention, Centros para el Control y la Prevención de Enfermedades, Centers for Disease Control, U.S. Centers for Disease Control and Prevention, CDC, U.S. CDC

### **Funding Body Type**

Government organisation

### **Funding Body Subtype**

National government

### Location

United States of America

### **Funder Name**

PATH

### Alternative Name(s)

Program for Appropriate Technology in Health

## **Funding Body Type**

Government organisation

### **Funding Body Subtype**

Other non-profit organizations

### Location

United States of America

### Funder Name

World Health Organization (WHO) (Switzerland) (ref: RPC170)

### Alternative Name(s)

, , Всемирная организация здравоохранения, Organisation mondiale de la Santé, Organización Mundial de la Salud, WHO, , BO3, OMS

### **Funding Body Type**

Private sector organisation

### **Funding Body Subtype**

International organizations

### Location

# **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?
Abstract results	Interim results of phase I			No	No