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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	Recruitment status	[_] Prospectively registered
04/10/2006	No longer recruiting	[_] Protocol
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)
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United States of America
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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, , ВОЗ, OMS

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	Interim results of phase I			No	No