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Assessment of Needle-free Disposable-syringe Jet Injector (DSJI) ID Dose-sparing of Pandemic A H1N1 Influenza Vaccine

The recruitment status of this study is unknown because the information has not been verified recently.

Verified June 2012 by University of Sao Paulo General Hospital.
Recruitment status was Not yet recruiting

Sponsor:
University of Sao Paulo General Hospital

Collaborators:
D'Antonio Consultants International
Sao Paulo, Secretaria de Estado da Saúde

Information provided by (Responsible Party):
University of Sao Paulo General Hospital

ClinicalTrials.gov Identifier:
NCT01582633

First received: April 19, 2012
Last updated: June 20, 2012
Last verified: June 2012
History of Changes

Purpose

This study will evaluate the immunological response and the safety profiles of seasonal, inactivated vaccine which contains in its composition the A/California/7/2009 H1N1 "pandemic" influenza virus, delivered via ID in reduced dose (0,1 mL) and (0,2 mL), and via IM in full dose (0,5 mL) delivered with needle-free, disposable-syringe jet injector, and control group with via IM in full dose (0,5 mL) delivered syringes and needles in subjects from 42 to 60 years old.

Reduced doses into the skin will be delivered by an investigational intradermal model of a licensed, needle-free, disposable-syringe jet injector (DSJI) system, LECTRAJET® M3 RA manufactured by D'Antonio Consultants International, Inc. DSJIs avoid the drawbacks and dangers of conventional needle-syringe injection. Delivery by DSJI into the skin is also rapid and simple and overcomes the difficulty and patient discomfort of the traditional Mantoux needle method for skin injection, as used for BCG vaccination and tuberculosis skin testing.

Participants will be assessed for local and systemic adverse events by clinical observation immediately after injection and then upon return on day 21 after each injection. In addition, investigators will call participants by telephone on days 2 and 7 days to collect information local and systemic side effects.

Serum will be collected on day 21 after each injection, and assayed for hemagglutination inhibition (HAI) using conventional methods performed by the Virology Lab of the Instituto de Medicina Tropical de São Paulo, blinded to the study arm allocations of each participant. Information about the adverse events would be collected on days 1, 3 and 7 after dose delivery. The investigators assessing adverse reactions will be blinded to the study arm to which each subject was allocated.

The primary endpoint of the study is to evaluate the vaccine's immunogenicity by HAI, each dose in accordance with international parameters which include: seroconversion or significant title increase (SCR), the frequencies by study arm of seroprotection defined as a post-vaccination titer of >40 (1/dil) (SPR), as well as the Geometric Mean Titers (GMTRs) of post-vaccination sera.

Condition	Intervention	Phase
Influenza	Biological: 2012 trivalent influenza vaccine	Phase 2 Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Single Blind (Outcomes Assessor)
Primary Purpose: Prevention

Official Title: Assessment of Dose-sparing of Pandemic A/California/7/2009 H1N1 Influenza Vaccine Administered Intradermally by Needle-free Disposable-syringe Jet Injector (DSJI)

Resource links provided by NLM:

MedlinePlus related topics: Flu

Drug Information available for: Influenza Vaccines

U.S. FDA Resources

Further study details as provided by University of Sao Paulo General Hospital:

Primary Outcome Measures:

- Immunogenicity [Time Frame: 21 days] [Designated as safety issue: No]

  Assess whether the experimental and standard dosages/delivery routes (ID and IM) for each age group met all modified criteria for assessment of influenza vaccines 21 days after vaccination for soroconversion for A/California/7/2009 H1N1 influenza virus.

Secondary Outcome Measures:

- Safety [Time Frame: 21 days] [Designated as safety issue: Yes]

  Evaluate frequency and severity of local and systemic adverse events following immunization between investigational (reduced dose) and control (standard dose) adult groups up to 21 days after vaccination in accordance with the definitions of the Brighton Collaboration Group.

- Seasonal influenza immunogenicity [Time Frame: 21 days] [Designated as safety issue: No]

  Assess whether the experimental and standard dosages/delivery routes (ID and IM) for each age group met all modified criteria for assessment of influenza vaccines 21 days after vaccination for soroconversion for 2012 seasonal influenza viruses.

Estimated Enrollment: 300

Study Start Date: July 2012
Estimated Study Completion Date: September 2012
Estimated Primary Completion Date: August 2012 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 0.1 ml ID dose Dose of 0.1 ml ID trivalent 2012 influenza vaccine administered by disposable needle-free jet injector	Biological: 2012 trivalent influenza vaccine 2012 trivalent influenza vaccine: • influenza A/California/7/2009 (H1N1) • influenza A/Perth/16/2009 (H3N2) • influenza B/Brisbane/60/2008 Single dose. Other Name: 2012 trivalent influenza vaccine
Experimental: 0.2 ml ID dose Dose of 0.2 ml ID trivalent 2012 influenza vaccine administered by disposable needle-free jet injector	Biological: 2012 trivalent influenza vaccine 2012 trivalent influenza vaccine: • influenza A/California/7/2009 (H1N1) • influenza A/Perth/16/2009 (H3N2) • influenza B/Brisbane/60/2008 Single dose. Other Name: 2012 trivalent influenza vaccine
Experimental: 0.5 ml IM dose - needle-free Dose of 0.5 ml IM trivalent 2012 influenza vaccine administered by disposable needle-free jet injector	Biological: 2012 trivalent influenza vaccine 2012 trivalent influenza vaccine: • influenza A/California/7/2009 (H1N1) • influenza A/Perth/16/2009 (H3N2) • influenza B/Brisbane/60/2008 Single

	dose. Other Name: 2012 trivalent influenza vaccine
Active Comparator: 0.5 ml IM - needle and syringe Dose of 0.5 ml IM trivalent 2012 influenza vaccine administered by needle and syringe	Biological: 2012 trivalent influenza vaccine 2012 trivalent influenza vaccine: • influenza A/California/7/2009 (H1N1) • influenza A/Perth/16/2009 (H3N2) • influenza B/Brisbane/60/2008 Single dose. Other Name: 2012 trivalent influenza vaccine

Detailed Description:
This study will evaluate the immunological response and the safety profiles of seasonal, inactivated vaccine which contains in its composition the A/California/7/2009 H1N1 "pandemic" influenza virus, delivered via ID in reduced dose (0,1 mL) and (0,2 mL), and via IM in full dose (0,5 mL) delivered with needle-free, disposable-syringe jet injector, and control group with via IM in full dose (0,5 mL) delivered syringes and needles in subjects from 42 to 60 years old.

Reduced doses into the skin will be delivered by an investigational intradermal model of a licensed, needle-free, disposable-syringe jet injector (DSJI) system, LECTRAJET® M3 RA manufactured by D'Antonio Consultants International, Inc. (East Syracuse, NY, USA) . DSJIs avoid the drawbacks and dangers of conventional needle-syringe injection. Delivery by DSJI into the skin is also rapid and simple and overcomes the difficulty and patient discomfort of the traditional Mantoux needle method for skin injection, as used for BCG vaccination and tuberculosis skin testing.

Participants will be assessed for local and systemic adverse events by clinical observation immediately after injection and then upon return on day 21 after each injection. In addition, investigators will call participants by telephone on days 2 and 7 days to collect information local and systemic side effects. Adverse events will be classified and analyzed according to case definitions established by the Brighton Collaboration Group.

Serum will be collected on day 21 after each injection, and assayed for hemagglutination inhibition (HAI) using conventional methods performed by the Virology Lab of the Instituto de Medicina Tropical de São Paulo, blinded to the study arm allocations of each participant. Information about the adverse events would be collected on days 1, 3 and 7 after dose delivery. The investigators assessing adverse reactions will be blinded to the study arm to which each subject was allocated.

The primary endpoint of the study is to evaluate the vaccine's immunogenicity by HAI, each dose in accordance with international parameters which include: seroconversion or significant title increase (SCR), the frequencies by study arm of seroprotection defined as a post-vaccination titer of >40 (1/dil) (SPR), as well as the Geometric Mean Titers (GMTRs) of post-vaccination sera.

Participants will be excluded if they have a prior history of influenza disease caused by A/California/7/2009 H1N1 or prior vaccination for same, among other exclusion and inclusion criteria to apply. Participants will be excluded retroactively from analysis if their pre-vaccination HAI assay discovers pre-existing seroprotective titers of >40 against pandemic virus, representing preexisting H1N1 exposure or vaccination

Eligibility

Ages Eligible for Study:	42 Years to 60 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	Yes

Criteria
Inclusion Criteria:

- Between 42 and up to 60 years of age.
- Available for follow up visits, at least at day 21.
- Written informed consent signed by the volunteer after reading and explanation.

Exclusion Criteria:

- Suspect or verified diagnosis of congenital or acquired immunodeficiency including AIDS.
- Suspect or verified diagnosis of malignant neoplasia, other than basocellular carcinoma.
- Volunteer ongoing treatment with high doses of systemic corticosteroids (equivalent to prednisone (2 mg/kg/d for more than two weeks) or on immunosuppressant therapy.
- Received or planning to receive a vaccine with live attenuated strain of virus within 30 days of the intended day(s) of study vaccination(s).
- Verified diagnosis of Influenza A/California/H1N1 or has already been immunized against (Influenza A/California/H1N1).
- Suspect or confirmed pregnancy (no need of pregnancy test, information on possible pregnancy is enough. These cases must be referred to routine vaccination).
- Suspect or verified diagnosis of hypersensitivity to any ingredient of the vaccine, to egg proteins or any component of the vaccine or life-threatening reactions after previous administration of any influenza vaccine.
- Any other circumstances that may potentially damage the minor or prevent procedures from being carried out according to evaluation of the

research team.

- Volunteer shows signs or symptoms of an active intercurrent disease (e.g. fever, rash, etc.) that may interfere with the evaluation of adverse events following immunization at the research team's discretion.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01582633

Contacts

Contact: Glacus Brito, MD 551138731562 glacus@usp.br

Locations

Brazil

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Principal Investigator: Glacus Brito, MD

Sponsors and Collaborators

University of Sao Paulo General Hospital

D'Antonio Consultants International

Sao Paulo, Secretaria de Estado da Saúde

Investigators

Principal Investigator: Glacus Brito, MD Hosp das Clinicas da Faculdade de Medicina da Universidade de Sao Paulo

More Information

No publications provided

Responsible Party:	University of Sao Paulo General Hospital
ClinicalTrials.gov Identifier:	NCT01582633 History of Changes
Other Study ID Numbers:	CAPPesq 0015/2010
Study First Received:	April 19, 2012
Last Updated:	June 20, 2012
Health Authority:	Brazil: National Health Surveillance Agency

Keywords provided by University of Sao Paulo General Hospital:
vaccine
influenza
needle free jet injector
Intradermal
sparing dose

Additional relevant MeSH terms:

Influenza, Human	Respiratory Tract Diseases
Orthomyxoviridae Infections	Respiratory Tract Infections
RNA Virus Infections	Virus Diseases

ClinicalTrials.gov processed this record on November 27, 2014