Eligibility Criteria and Visit Schedule (SLVP website link)
Metabolic and Immune Responses to TIV in Patients with Mitochondrial Disease

This segment of the Vaccine Program website is designed to provide more detailed information to volunteers who are interested in participating in the influenza vaccine study. There are three sections:
  a. Section 1: Inclusion Criteria - List of eligibility requirements for participation.
  b. Section 2: Exclusion Criteria - Events or conditions that might make you ineligible to participate.
  c. Section 3: Table of study visits and procedures. This will give you a better idea of the study requirements and the time commitment involved.

Eligibility Criteria

Section 1: To be considered, you must meet these requirements:

1) 13-50 years of age (volunteers diagnosed with MELAS) or 18-50 years of age (healthy control volunteers)
2) General good health at time of enrollment
3) Willing and able to sign Informed Consent
4) Available for follow-up for the planned duration of the study
5) Acceptable medical history by screening evaluation and brief clinical assessment

Section 2: To be considered, you must not have any of these events or conditions that could put your health at risk if you were to participate in the study.

1) Allergy to egg or egg products or allergy to vaccine components, including thimerosal
2) Active systemic or serious concurrent illness, including febrile illness, within the 3 days prior to vaccination
3) History of immunodeficiency, known or suspected impairment of immunologic function, including, but not limited to, clinically significant liver disease, diabetes mellitus treated with insulin, moderate to severe renal disease, blood pressure >150/95 at screening, or any other chronic disorder which, in the opinion of the investigator, might jeopardize volunteer safety or compliance with the protocol.
4) Hospitalization in the past year for congestive heart failure or emphysema.
5) History of chronic Hepatitis B or C.
6) Recent or current use of immunosuppressive medication, including glucocorticoids (corticosteroid nasal sprays are permissible).
7) Malignancy, other than squamous cell or basal cell skin cancer (includes solid tumors such as breast cancer or prostate cancer with recurrence in the past year, and any hematologic cancer such as leukemia).
8) Autoimmune disease (including rheumatoid arthritis treated with immunosuppressive medication such as Plaquenil, methotrexate, prednisone, Enbrel) which, in the opinion of the investigator, might jeopardize volunteer safety or compliance with the protocol.
9) History of blood dyscrasias, renal disease, or hemoglobinopathies requiring regular medical follow up or hospitalization during the preceding year
10) Receipt of blood or blood products within the past 6 months
11) Medical or psychiatric condition or occupational responsibilities that preclude subject compliance with the protocol
12) Inactivated vaccine 14 days prior to vaccination or live, attenuated vaccine within 60 days of vaccination
13) History of Guillain–Barré Syndrome
14) Pregnant or lactating woman
15) Use of investigational agents within 30 days prior to enrollment
16) Donation of the equivalent of a unit of blood within 6 weeks prior to enrollment
17) Any condition which, in the opinion of the investigator, might interfere with volunteer safety, study objectives or the ability of the participant to understand or comply with the study protocol

Visit Schedule

Section 3: Study Visits/ Schedule
There will be 4 clinic visits at Stanford within a one month-period (September 2010 – January 2011). You will receive a single dose of the influenza vaccine by intramuscular (IM) injection (TIV). The second clinic appointment will be approximately six hours after the vaccination. The third clinic visit will be between 5-7 days after the vaccination. The fourth and last clinic visit will be between 26-30 days after the vaccination. There will be a blood draw at each of the four clinic visits. The first clinic visit will require approximately 1 to 1 1/2 hours to complete. The remaining 3 visits will take approximately 25 minutes each. The visit schedule is as follows:

<table>
<thead>
<tr>
<th>Window</th>
<th>Visit Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>September 2010– January 2011</strong></td>
<td></td>
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<tr>
<td>Visit 1, Day 0</td>
<td>Consent explained and signed by volunteer. Volunteer will receive single dose seasonal flu vaccine by injection into the upper arm muscle and observed in the clinic for 30 minutes following vaccination. Volunteer will complete study forms and instructions for completing a 7-day diary card will be given. Blood draw.</td>
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<tr>
<td>Visit 2, Day 0:</td>
<td>Blood draw and review of diary card and review of health status. Vaccination site will be assessed.</td>
</tr>
<tr>
<td>Six hours after Visit 1</td>
<td>20 to 30 minutes</td>
</tr>
<tr>
<td>Visit 3, Day 5-7:</td>
<td>Blood draw, review of diary card, and review of health status. Vaccination site will be assessed.</td>
</tr>
<tr>
<td>20 to 30 minutes</td>
<td></td>
</tr>
<tr>
<td>Visit 4, Day 26-30:</td>
<td>Blood draw, review of diary card, and review of health status. Vaccination site will be assessed.</td>
</tr>
<tr>
<td>20 to 30 minutes</td>
<td></td>
</tr>
</tbody>
</table>

Thank you for your interest in our research. Please contact the study staff at (650) 498-7284 or email us at vaccines_program@stanford.edu if you have any questions. We look forward to talking with you.