Eligibility Criteria and Visit Schedule (SLVP website link)

U19 CCHI: Adaptive and Innate Immunity, Memory and Repertoire in Vaccination and Infection Project 1: The role of CD4+ memory phenotype, memory, and effector T cells in vaccination and infection 2014-2019

This segment of the Vaccine Program website is designed to provide more detailed information to volunteers who are interested in participating in the study. There are three sections.

In the first section you will find a list of requirements you will need to meet in order to be considered for participation.

In the next section you will find events or conditions that might make you ineligible to participate.

In the last section you will find a table of study visits and procedures. This will give you a better idea of the study requirements and the time commitment involved.

Eligibility Requirements:

Section I. To be considered, you should meet these requirements:

1. Otherwise healthy non-twins 6 months - 10 years old, or 2-5 year old identical (MZ) twins.
2. Willing to complete the informed consent process (including assent for minors 7 years old and above).
3. Availability for follow-up for the planned duration of the study (annually for up to 5 years)
4. Acceptable medical history by review of inclusion/exclusion criteria and vital signs.
5. Willing to have primary care physician immunize child with the MMRV vaccine (Group E only) and return for a study visit 60 days later.

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

1. Prior off-study vaccination with the current year's seasonal influenza vaccine.
2. Life-threatening reactions to previous influenza vaccinations
3. Asthma or history of wheezing (for LAIV4 only)
4. Allergy to egg or egg products, or to vaccine components, including gentamicin, gelatin, arginine or MSG (for LAIV4 only)
5. Concomitant aspirin therapy in children and adolescents
6. Active systemic or serious concurrent illness, including febrile illness on the day of vaccination
7. History of immunodeficiency (including HIV infection)
8. 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, or any other chronic disorder which, in the opinion of the investigator, might jeopardize volunteer safety or compliance with the protocol.
9. Chronic Hepatitis B or C.
10. Recent or current use of immunosuppressive medication, including systemic glucocorticoids (corticosteroid nasal sprays and topical steroids are permissible in all groups; inhaled steroid use is not permissible)
11. Participants in close contact with anyone who has a severely weakened immune system should not receive LAIV4.
12. Malignancy
13. 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.

14. History of blood dyscrasias, renal disease, or hemoglobinopathies requiring regular medical follow up or hospitalization during the preceding year
15. Receipt of blood or blood products within the past 6 months or planned used during the study.
16. Receipt of Inactivated vaccine 14 days prior to study enrollment, or planned vaccinations prior to completion of last study visit (~ 28 Day after study vaccination)
17. Receipt of live, attenuated vaccine within 60 days prior to enrollment of planned vaccination prior to completion of last study visit (~ 28 Day after study vaccination)
18. Need for allergy immunization (that cannot be postponed) during the study period.
19. History of Guillain–Barré syndrome
20. Use of investigational agents within 30 days prior to enrollment or planned use during the study.
21. Donation of the equivalent of a unit of blood within 6 weeks prior to enrollment or planned donation prior to completion of the last visit.
22. 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.

Scheduling Appointments:

Section III**. Study Visits**

For all volunteers there will be total of 2- 4 clinic visits every year for the next 5 years. At Visit 1, we will review informed consent and study eligibility. The first clinic visit will require approximately 1 hour completing. Your child will receive a FDA licensed seasonal vaccine at this visit. This is the same vaccine that will be used for public during the fall flu season. The remaining visits will take approximately 20-30 minutes each. For those children who have never received an influenza vaccination, we will follow the recommendation that the Advisory Committee on Immunization Practices (ACIP) has made to the Centers for Disease Control and Prevention (CDC). The ACIP recommends administration of a second dose of the flu vaccine at least 28 days after initial vaccination. Study volunteers who have not previously been vaccinated will return to the clinic 28–32 days after their first visit to receive their second dose of flu vaccine (which will be the same preparation as the first vaccine). All the visits will be at an outpatient clinic at Stanford - located in the Freidenrich Center for Translational Research (FCTR) at 800 Welch Road, Palo, CA 94304. Your child will be assigned to the following groups based on age and twin/non-twin status:

2-5 years old identical twin: Your twins will receive a quadrivalent live-attenuated influenza vaccine given as nasal spray vaccine at their first visit. Your child's participation in the study will last for approximately 2–3 months, depending on whether he/she has had the flu vaccine in a prior year. Children will come in for 3-4 clinic visits first year and then 3 visits in the subsequent years for up to 5 years. A small amount of blood will be collected at some of the visits.

6month-10 years old non-twin: Your child will receive either a quadrivalent live-attenuated influenza vaccine given as nasal spray vaccine or an inactivated influenza vaccine as an injection. Your child's participation in the study will last for approximately 2–3 months, depending on whether he/she has had the flu vaccine in a prior year. Children will come in for 2-3 clinic visits in the first year and then 2 visits in the subsequent years for up to 5 years. A small amount of blood will be collected at some of the visits.

6-12 month old non-twin: Your child will receive two dose of flu vaccine at your first year of study participation since your child has never received a flu immunization before. We will follow the recommendation that the Advisory Committee on Immunization Practices (ACIP) has made to the Centers for Disease Control and Prevention (CDC). Study volunteers will return to the clinic 28–32 days after their first visit to receive their second dose of flu vaccine (which will be the same preparation as the first vaccine). You will be asked to return to our clinic 60± 7 days after your second dose of flu vaccine for a follow-up visit. Volunteers will be given the first dose of the MMRV vaccine at approximately 12-

15 months of age (to be administered by the volunteer's personal pediatrician). The volunteer will be asked to return to our clinic for a study visit 60± 7 days post-initial MMRV vaccination. Blood samples will be collected at some of the visits. After initial year of participation volunteer will return for only 2 visits including annual flu vaccination and blood sample collection for up to 5 years.

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.

For general information about participant rights, contact 1-866-680-2906