High vs.Standard Dose Influenza Vaccine in Pediatric Solid Organ Transplant (SOT) Recipients

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 3 years to 17 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. Male or female, 3-17 years of age at time of enrollment
2. Pediatric kidney, heart, and/or liver transplant recipient ≥1 month and <24 months post-transplant at the time of study immunization

- Note: Inclusion of recipients of multiple organs is permitted but is limited to recipients of any combination of organs including kidney, heart and/or liver
- Note: Participants undergoing re-transplantation are permitted
    1. Anticipated to be available for duration of the study
    2. Available by telephone, email, or text message

Exclusion Criteria:

1. Inability (i.e. not able to understand and provide consent) or unwillingness of a participant/parent/legal guardian to give written informed consent or comply with study protocol
2. History of severe hypersensitivity to influenza vaccination or anaphylaxis to eggs/egg protein
3. History of severe latex hypersensitivity
4. History of Guillain-Barre syndrome
5. History of lung or intestine transplant
6. HIV positive patients (testing within 24 months of enrollment)
7. Receipt of current season's influenza vaccine post-transplant prior to enrollment in the study
8. Currently pregnant or lactating (females of childbearing age may be enrolled based on self-report, urine pregnancy test must be performed prior to each influenza vaccine)
9. Past or current medical problems or findings from physical examination or laboratory testing that are not listed above, which, in the opinion of the investigator, may pose additional risks from participation in the study, may interfere with the participant's ability to comply with study requirements or that may impact the quality or interpretation of the data obtained from the study.

Conditions & Interventions

Interventions:
BIOLOGICAL: Standard Dose Quadrivalent Inactivated Influenza Vaccine, BIOLOGICAL: High Dose Quadrivalent Inactivated Influenza Vaccine
Conditions:
Immunization, Infection, Transplantation Infection, Influenza
Keywords:
Influenza, Vaccination, Immunization, High Dose, Fluzone, Standard Dose, Influenza, Human, Communicable Diseases, Pediatric transplantation

More Information

Description:
Influenza virus is a significant pathogen in pediatric solid organ transplant (SOT) recipients. However, these individuals respond poorly to standard-dose (SD) inactivated influenza vaccine (IIV). Recent studies have investigated two strategies to overcome poor immune responses in SOT recipients: (1) administration of high-dose (HD)-IIV compared to SD-IIV and (2) two doses of SD-IIV compared to one dose of SD-IIV in the same influenza season. One study compared HD-IIV vs. SD-IIV in adult SOT recipients and noted that HD-IIV was safe and more immunogenic; however, the median post-transplant period was 38 months. A phase I pediatric study comparing a single dose of HD-IIV vs. SD-IIV was safe with higher immunogenicity, but the study was limited by small sample size and median post-transplant vaccine administration was 26 months. In another phase II trial of adult SOT recipients, two doses of SD-IIV one month apart compared to one-dose of SD-IIV revealed modestly increased immunogenicity when given at a median of 18 months post-transplant. Therefore, these studies lack both evaluation in the early post-transplant period and substantive pediatric populations. Additionally, the administration of two-doses of HD-IIV in the same influenza season has not been evaluated in pediatric SOT recipients. Thus, the optimal immunization strategy for pediatric SOT recipients less than 24 months post-transplant is unknown. In addition, immunologic predictors and correlates of influenza vaccine immunogenicity in pediatric SOT recipients have not been well-defined. The central hypothesis of our proposal is that pediatric SOT recipients 1-23 months post-transplant who receive two doses of HD-quadrivalent inactivated influenza vaccine (QIV) will have similar safety but higher Hemagglutination Inhibition (HAI) geometric mean titers (GMTs) to influenza antigens compared to pediatric SOT recipients receiving two doses of SD-QIV.

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