

Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Pass RF, Zhang C, Evans A, et al. Vaccine prevention of maternal cytomegalovirus infection. *N Engl J Med* 2009;360:1191-9.

**A Phase II, Randomized, Double-Blind, Placebo-Controlled,
Clinical Trial of Recombinant CMV gB Vaccine in Postpartum Women**

ADMISSION CRITERIA (SUBJECT ELIGIBILITY)

Subjects must satisfy all of the following criteria:

A. Inclusion Criteria

- 1) Mothers, 14 to 40 years of age (inclusive), who have delivered a newborn infant within the previous 12 months, reside within the Birmingham metropolitan area, or the Tuscaloosa county area, and sign an informed consent form following a detailed explanation of the study.
- 2) CMV seronegative as determined by the AxSYM® System CMV IgG antibody assay (Abbott Diagnostics) performed within 14 weeks prior to the first immunization.
- 3) In good health as judged by medical history obtained by patient interview and physical examination.
- 4) Willing to participate with 4 follow-up visits per year for 3 years after the third dose of vaccine.
- 5) Volunteers must be willing to use an effective means of contraception of their choice from the first dose of vaccine up to 2 months after the third dose of vaccine.

Methods that will be considered effective for the purposes of this clinical trial include any hormonal contraceptive, double barrier methods and abstinence.

B. Exclusion Criteria

- 1) Known maternal immune disorder such as HIV infection, collagen vascular disease, immune deficiency, or chronic disease requiring treatment with immunosuppressive medication.
- 2) Chronic disease such as diabetes, sickle cell disease, heart disease, fibromyalgia, arthritis or asthma requiring medication.

Patients with a diagnosis of asthma or past asthma will be allowed to enroll if they do not currently take medication for asthma and have been off asthma medication and free from asthma symptoms for at least 2 years. Patients with mild to moderate essential hypertension on medication will be allowed if their blood pressure is controlled within the normal range for at least one month.

3) Positive rapid test for HIV antibody.

All subjects will be tested for HIV antibody using a rapid serologic test at the time of enrollment. Subjects will be provided pre-test counseling before the test is performed and post-test counseling when the subject is informed of the test results. This counseling is provided by the study nurses according to CDC guidelines [Centers for Disease Control and Prevention. Revised Guidelines for HIV Counseling, Testing and Referral and Revised Recommendations for HIV Screening of Pregnant Women. *MMWR* 2001; 50 (No. RR-19)]. Subjects who are eligible for this study are considered very unlikely to be HIV positive because almost all adults who are HIV positive are also CMV positive and almost all potential enrollees will have received HIV screening during their recent pregnancy. If a subject is found to be HIV positive, she will receive post-test counseling and referred to a HIV medical care provider.

4) Maternal sterilization procedure planned in the postpartum period.

5) Current use of steroids or other immunosuppressive medications.

6) Maternal drug or alcohol abuse.

7) Mothers who are nursing their infants.

8) Participation in a clinical trial of another investigational vaccine or drug, if they have received the investigational drug or vaccine within 6 months prior to enrollment date for this trial.

9) A history of anaphylaxis or serious vaccine reactions.

10) Previous receipt of CMV vaccine.

11) Receipt of blood products within 3 months prior to study enrollment.