Reply to Anderson and Rouse

To the Editor—I thank Anderson and Rouse for their comments [1]. Regarding the use of passive immunization for cytomegalovirus (CMV) infections during pregnancy, the original study by Nigro et al described 2 distinct protocols for the use of CMV hyperimmune globulin, 1 to prevent fetal infection and the other for treatment of infected fetuses [2]. Randomized trials for both uses would be optimal; however, for many reasons, no randomized trials are ongoing or being contemplated for treatment of infected fetuses. Therefore my editorial commentary was clearly directed toward treatment options [1, 3]. For prevention, 1 randomized trial, which used the identical Nigro prevention protocol, was not negative but rather showed an efficacy rate lower than but consistent with that observed by Nigro et al for the prevention of fetal infection. The good news is that for the prevention of fetal infection after primary maternal infection during pregnancy there are 2 important clinical trials in progress. One trial in the United States is sponsored by the Eunice Kennedy Shriver National Institutes of Child Health and Human Development Maternal Fetal Medicine Units Network, and enrollment just commenced. It is a double-blinded, randomized, placebo-controlled trial that will enroll 800 women at 14 centers across the United States and will have adequate power to detect a one-third reduction in the rate of congenital infection with the use of CMV hyperimmune globulin. The other trial is in Europe, is sponsored by Biotest, and is a randomized, open label trial. Both trials serologically screen pregnant women for antibodies to CMV, and those who seroconvert in the first 36 weeks of gestation are randomized to receive either monthly hyperimmune globulin or nothing. Successful enrollment and completion of both trials is essential for determining the true efficacy of prophylactic hyperimmune globulin during pregnancy.
Note

Potential conflicts of interest. Author certifies no potential conflicts of interest.

The author has submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

Stuart P. Adler
Departments of Pediatrics and Microbiology, Virginia Commonwealth University, Richmond

References


Correspondence: Stuart P. Adler, MD, Division of Pediatrics Infectious Diseases, Department of Pediatrics, Virginia Commonwealth University, 1101 E Marshall St, 12-051 Sanger Hall, Richmond, Virginia 23228 (sadler@vcu.edu).

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